

# At-a-glance: Psychotropic drug information—including side effects, teratogenic risks and recommended clinical monitoring for select drugs—for children and adolescents

*From “Appropriate Use of Psychotropic Drugs in Children and Adolescents: A Clinical Monograph” appendices*

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## Keywords

children’s mental health, children’s behavioral health, psychotropic drugs in children, antidepressant medications in children, antipsychotic medications in children, mood stabilizing medications in children, anticonvulsant medications in children, anti-anxiety medications in children, ADHD medications in children, stimulant medications in children, foster care, child mood disorders, child bipolar disorder, child major depressive disorder, child OCD, child anxiety disorders, child PTSD, child disruptive behavioral disorders, child aggression, child ADHD, child schizophrenia, child eating disorders, developmental disabilities

*The following medication charts are intended to provide general information on dosing, clinical indications, ages approved for usage, specific drug warnings/precautions, typical side effects, teratogenic risks and appropriate patient monitoring parameters.*

# At-a-glance: Psychotropic drug information for children and adolescents

## Antipsychotic Medications

*Black Box Warning for all atypical/second generation antipsychotics (SGAs):* Increased mortality in elderly patients with dementia-related psychosis.

*\*Precautions which apply to all atypical or SGAs:* Neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia, diabetes, weight gain, akathisia and dyslipidemia.

*†Precautions which apply to all typical or first-generation antipsychotics (FGAs):* EPS, tardive dyskinesia.

| Drug Brand Name / Generic Name         | FDA Approved Age / Indication  | Pediatric Dosage / Serum Level When Applicable | Black Box Warnings / Warnings and Precautions / Additional Information   |
|--|--|--|--|
| Abilify <i>aripiprazole</i> *<br>(SGA) | Irritability associated with autistic disorder: 6 and older  | 2–15 mg daily<br><br>< 50 kg: 2–10 mg daily    | <i>Additional Black Box Warning:</i> Increased risk of suicidal thinking and behavior in short-term studies in children, adolescents and young adults taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors.<br><br><i>Warnings and precautions:</i> 1) May cause extrapyramidal disorder, somnolence, tremor, fatigue, nausea, akathisia, blurred vision, excessive saliva, sedation, drooling, decreased appetite, lethargy, fever, headache, increased appetite, nasopharyngitis and dizziness. 2) Patients can experience intense urges for gambling and other compulsive behaviors (shopping, eating, sexual urges, etc. 3) Abilify Maintena and Aristada, long-acting injectable versions of this product, are not approved in pediatric populations. |
|  | Tourette’s Disorder: 6 and older   | > 50 kg: 2–20 mg daily                         |  |
|  | Bipolar I disorder, acute manic or mixed episodes, monotherapy or as an adjunct to lithium: 10 and older | 2–30 mg daily                                  |  |

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|                                    | Schizophrenia: 13 and older      | 2–30 mg daily<br><br>30 mg/day was not found to be more effective than the 10 mg/day dose | <p><i>Pregnancy:</i> No adequate or well controlled studies in pregnant women. In animal studies, aripiprazole demonstrated developmental toxicity, included possible teratogenic effects. If treatment is initiated during pregnancy, use of an agent other than aripiprazole is preferred.</p> <p><i>Lactation:</i> Aripiprazole is excreted in human breast milk. use of agents other than aripiprazole in breastfeeding women is preferred.</p>   |
| Saphris <i>asenapine*</i><br>(SGA) | Bipolar mania: 10–17             | 2.5–10 mg twice daily   | <p><i>Warnings precautions and administration:</i> 1) Can cause QT prolongation, seizures, somnolence, dizziness, nausea, increased appetite, weight gain, fatigue, metallic taste in mouth and oral tingling. 2) Contraindicated in those with severe hepatic impairment. 3) Efficacy of asenapine was NOT demonstrated in clinical trials of adolescents aged 12–17 with schizophrenia. 4) Asenapine is a sublingual tablet. It should not be swallowed but should be placed under the tongue and left to dissolve completely. The tablet will dissolve in saliva within seconds. Eating and drinking should be avoided for 10 minutes after administration. 5) Available in black cherry flavor.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. If treatment is needed in a woman planning a pregnancy, use of an agent other than asenapine is preferred.</p> |

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|  |  |   | <i>Lactation:</i> It is not known if asenapine is excreted in human breast milk. It is excreted in the milk of rats during lactation.   |
| Rexulti <i>brexpiprazole</i><br>(SGA)                    | 18 and older                                       | Safety and efficacy of brexpiprazole in pediatric patients have not been established              | <p><i>Additional Black Box Warnings:</i> 1) Antidepressants increase the risk of suicidal thoughts and behaviors in patients aged 24 years and younger. Monitor for clinical worsening and emergence of suicidal thoughts and behaviors. 2) Safety and effectiveness of Rexulti have not been established in pediatric patients.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. No teratogenic effects were seen in animal studies.</p> <p><i>Lactation:</i> It is not known if brexpiprazole and its metabolites are excreted in human breast milk. It is distributed into milk in rats.</p> |
| Vraylar <i>cariprazine</i><br>(SGA)                      | 18 and older                                       | N/A   | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. There are no available data use in pregnant women to inform any drug-associated risks for birth defects or miscarriage. The major active metabolite of cariprazine, didesmethyl-cariprazine, has been detected in adult patients up to 12 weeks after discontinuation. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> It is not known if cariprazine is excreted in human breast milk. It is excreted in the milk of rats during lactation.</p>  |
| Thorazine<br><i>chlorpromazine</i> <sup>†</sup><br>(FGA) | Severe behavioral problems marked by combativeness | Hospitalized patients: start with low doses and increase gradually. In severe behavior disorders, | <i>Warnings and precautions:</i> 1) May alter cardiac conduction and cause sedation, Neuroleptic Malignant Syndrome and weight gain. 2) Use caution with renal disease, seizure   |

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|                                      | <p>and/or explosive hyperexcitable behavior and short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms:<br/>impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance: 6 months and older</p> <p>Nausea and vomiting: 6 months and older<br/>Presurgical apprehension: 6 months and older</p> | <p>higher dosages may be necessary; 50–100 mg daily. 200 mg daily in older children.</p> <p>Oral: 0.55 mg/kg/dose every 4–6 hours as needed</p> <p>**There is little evidence that behavior improvement in severely disturbed mentally retarded patients is further enhanced by doses beyond 500 mg per day**</p> <p>Maximum recommended daily doses:</p> <p>Children younger than 5 years or weighing less than 22.7 kg: 40 mg/day<br/>Children ≥ 5 years and adolescents or weighing ≥ 22.7 kg: 75 mg/day; a maximum total dose of 100 mg has been used</p> | <p>disorders, respiratory disease and in acute illness. 3) Should generally not be used in pediatric patients under 6 months of age except when potentially lifesaving.</p> <p><i>Pregnancy:</i> Safety for the use of chlorpromazine during pregnancy has not been established. Reproductive studies in rats have demonstrated potential for embryotoxicity, increased neonatal mortality and decreased performance in offspring. The possibility of permanent neurological damage cannot be excluded.</p> <p><i>Lactation:</i> Chlorpromazine is excreted in human breast milk; concentrations may be higher than what is in the maternal plasma. A decision should be made whether to discontinue breastfeeding or to discontinue the drug, due to potential for serious adverse reactions in the infant.</p> |
| Clozaril <i>clozapine</i> *<br>(SGA) | 18 and older   | Limited data in pediatric and adolescent populations  | <p><i>Black Box Warnings:</i> 1) agranulocytosis, 2) seizures, 3) myocarditis and cardiomyopathy, 4) adverse cardiovascular and respiratory effects.</p> <p><i>Pregnancy:</i> No adequate or well controlled studies in pregnant women. Clozapine crosses the placenta and can be detected in fetal blood and amniotic fluid.</p>  |

| Drug Brand Name /<br>Generic Name           | FDA Approved Age /<br>Indication   | Pediatric Dosage / Serum Level<br>When Applicable   | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|---|--|---|--|
|   |  |   | <p><i>Lactation:</i> Clozapine is present in human breast milk. Use is not recommended.</p>  |
| <p>Haldol <i>haloperidol</i>†<br/>(FGA)</p> | <p>Schizophrenia: 3 and older</p>  | <p>Children 3–12 years weighing 15–40 kg: Oral: Initial: 0.5 mg/day in 2–3 divided dose</p> <p>Children &gt; 40 kg and Adolescents: Oral: 0.5–5 mg/day in 2–3 divided doses</p> | <p><i>Warnings and precautions:</i> 1) May cause sedation, orthostatic hypotension, photosensitivity, constipation, dry mouth and prolactin elevation. 2) Haldol decanoate, the long-acting injectable version of this product, is not approved in pediatrics.</p> <p><i>Pregnancy:</i> No adequate or well controlled studies in pregnant women. Haloperidol crosses the placenta in humans. Animal studies show haloperidol may harm fetus.</p> <p><i>Lactation:</i> Is found in breast milk and has been detected in the plasma and urine of breastfeeding infants. Breastfeeding is not recommended.</p> |
|   | <p>Tourette’s syndrome, and disruptive behavior disorder and ADHD: 3 and older</p> | <p>3–12 years weighing 15–40 kg: Oral: Initial: 0.5 mg/day in 2–3 divided doses</p> <p>&gt; 40 kg and adolescents: Oral: 0.25–15 mg/day in 2–3 divided doses</p>                |  |
| <p>Fanapt <i>iloperidone</i>*<br/>(SGA)</p> | <p>18 and older</p>  | <p>N/A</p>  | <p><i>Warnings and precautions:</i> 1) May cause prolonged QTc interval and priapism. 2) Not recommended for patients with severe liver impairment. 3) Use with caution in patients at risk of seizures or seizure history.</p> <p><i>Pregnancy:</i> The limited available data in pregnant women is not sufficient to inform a drug associated risk for major defects and miscarriage.</p> <p><i>Lactation:</i> It is not known if iloperidone and its metabolites are excreted in human milk. It is excreted in the milk of rats during lactation. Not recommended.</p>                                    |

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| Adasuve <i>loxapine</i> <sup>†</sup><br>(FGA)  | 18 and older                     | N/A   | <p><i>Additional Black Box Warning:</i> Can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest. Administer Adasuve only in an enrolled healthcare facility that has immediate access on-site to equipment and personnel trained to manage acute bronchospasm.</p> <p><i>Warnings and precautions:</i> 1) Adasuve is an inhaled form of loxapine. 2) Is only available through a restricted program under a risk evaluation and mitigation strategy (REMS) called Adasuve REMS.</p> <p><i>Pregnancy:</i> Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> It is not known whether loxapine is present in human breast milk. Loxapine and its metabolites are present in the breast milk of lactating dogs. Discontinue drug or nursing, taking into consideration importance of drug to mother.</p> |
| Loxitane <i>loxapine</i> <sup>†</sup><br>(FGA) | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) Should be used with extreme caution in patients with a history of convulsive disorders since it lowers seizure threshold. 2) Use with caution in those with cardiovascular disease.</p> <p><i>Pregnancy:</i> Adverse events have been observed in animal reproduction studies, may cause fetal harm.</p> <p><i>Lactation:</i> The extent of excretion in human milk is not known.</p>   |



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| Caplyta<br><i>lumateperone</i><br>(SGA) | 18 and older                        | N/A   | <p><i>Warnings, precautions and administration:</i> Avoid use in patients with moderate to severe hepatic disease or impairment. Use caution in patients at risk for seizures. Administer with food.</p> <p><i>Pregnancy:</i> Data collection to monitor pregnancy and infant outcomes following exposure to lumateperone is ongoing. If treatment is needed in a woman planning a pregnancy, use of another agent is preferred.</p> <p><i>Lactation:</i> It is not known if lumateperone is present in breast milk.</p>   |
| Latuda <i>lurasidone</i><br>(SGA)       | Schizophrenia: 13 and older         | 40–80 mg daily                                    | <p><i>Additional Black Box Warnings:</i> Increased risk of suicidal thinking and behavior in short-term studies of children, adolescents and young adults taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. No adverse developmental or teratogenic effects were seen in animal studies.</p> <p><i>Lactation:</i> It is not known if lurasidone and its metabolites are excreted in human breast milk. It is excreted in the milk of rats during lactation.</p> |
|   | Bipolar depression:<br>10 and older | 20–80 mg daily                                    |  |

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| Moban <i>molindone</i> <sup>†</sup><br>(FGA) | Schizophrenia: 12 and<br>older  | 15–225 mg daily depending on the<br>severity of the disorder and<br>response to treatment         | <p><i>Warnings and precautions:</i> Drowsiness is the most frequently occurring adverse effect.</p> <p><i>Pregnancy:</i> Adverse events were observed in some animal reproduction studies. The benefits must be weighed against the unknown risks to the fetus if used in pregnant patients.</p> <p><i>Lactation:</i> It is not known if molindone is excreted in human breast milk.</p>  |
| Zyprexa <i>olanzapine</i> *<br>(SGA)         | Schizophrenia and<br>bipolar I disorder,<br>mania or mixed<br>episodes: 13 and<br>older | 2.5–20 mg daily   | <p><i>Warnings and precautions:</i> 1) May cause sedation, increased appetite, weight gain, dizziness, abdominal pain, fatigue, dry mouth and headache. 2) Zyprexa Relprev, the long-acting injectable formulation, is not approved in pediatrics.</p> <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women.</p> <p><i>Lactation:</i> Olanzapine is excreted in human breast milk.</p>  |
| Invega <i>paliperidone</i> *<br>(SGA)        | Schizophrenia: 12 and<br>older  | 3 mg once daily<br><br>Max dose is weight dependent:<br>< 51kg: 6 mg daily<br>≥ 51kg: 12 mg daily | <p><i>Warnings and precautions:</i> 1) May cause somnolence, akathisia, tremor, dystonia, cogwheel rigidity, anxiety, weight gain and tachycardia. 2) Use can cause an increase in the QT interval. 3) Invega Sustenna and Invega Trinza, long-acting injectable formulations, are not approved in pediatrics.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. In animal reproduction studies, there were no increases in fetal abnormalities.</p> |

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| Trilafon<br><i>perphenazine</i> <sup>†</sup> (FGA) | Schizophrenia: 12 and<br>older       | Oral: 2–64 mg daily in divided<br>doses 2–4 times daily (12–24 mg is<br>average daily dose) | <p><i>Lactation:</i> Paliperidone is excreted in human breast milk.</p> <p><i>Warnings and precautions:</i> 1) May cause dystonia, neuroleptic malignant syndrome, orthostatic hypotension, weight gain, endocrine changes and alterations in cardiac condition. 2) According to the label, pediatric dosages have not been established but they recommended that pediatric patients over 12 years may receive the lowest limit of adult dosage.</p> <p><i>Pregnancy:</i> Jaundice or hyper-/hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Safe use in pregnancy has not been established.</p> <p><i>Lactation:</i> Perphenazine is present in breast milk. Safe use during lactation has not been established.</p> |
| Orap <i>pimozide</i> <sup>†</sup><br>(FGA)         | Tourette’s disorder:<br>12 and older | ≥ 12 years: 0.05–0.2 mg/kg once<br>daily; not to exceed 10 mg daily                         | <p><i>Warnings and precautions:</i> 1) May cause dyskinesias, dry mouth, constipation, prolactin elevation and prolonged QTc interval. 2) Avoid abrupt withdrawal. 3) A small, open label study (36 children) in children ages 2–12 demonstrated pimozide has a similar safety profile in this age group as in older patients and there were no safety findings that would preclude its use in this age group.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Adverse events were observed in some animal reproduction studies.</p> <p><i>Lactation:</i> It is not known whether pimozide is excreted in human breast milk.</p>  |

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| Seroquel<br><i>quetiapine*</i> (SGA)    | Bipolar I disorder:<br>10 and older | 25–600 mg daily                                   | <p><i>Warnings and precautions:</i> May cause somnolence, dizziness, fatigue, increased appetite, nausea, vomiting, dry mouth, tachycardia and weight gain. May cause hyperprolactinemia, which may decrease reproductive function in both males and females. The clinical significance of hyperprolactinemia in patients with breast cancer or other prolactin-dependent tumors is unknown. Use with caution in patients with decreased gastrointestinal motility as anticholinergic effects may exacerbate underlying condition. Use with caution in patients with hepatic disease or impairment; dosage adjustment may be required. Use with caution in patients at risk of seizures, or on concurrent therapy with medications which may lower seizure threshold.</p> <p><i>Pregnancy:</i> Crosses the placenta and can be detected in cord blood. Based on available data, congenital malformations have not been observed in humans. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (EPS) and/or withdrawal symptoms in newborns following delivery.</p> <p><i>Lactation:</i> Quetiapine is excreted in human breast milk. When an antipsychotic medication is needed in a breastfeeding woman, quetiapine may be used. In general, infants exposed to SGAs via breast milk should be monitored weekly for the first month of exposure for symptoms such as appetite changes, insomnia, irritability or lethargy.</p> |
|   | Schizophrenia: 13 and<br>older      | 25–800 mg daily                                   |   |
| Seroquel XR<br><i>quetiapine*</i> (SGA) | Bipolar I disorder:<br>10 and older | 50–600 mg daily                                   |   |
|   | Schizophrenia: 13 and<br>older      | 50–800 mg daily                                   |   |

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| Risperdal<br><i>risperidone*</i> (SGA) | Irritability associated<br>with autistic disorder:<br>5 and older | 15–20 kg: 0.25–3 mg daily<br><br>≥ 20 kg: 0.5–3 mg daily | <p><i>Warnings and precautions:</i> 1) Risperdal Consta, the long-acting injectable formulation, is not approved in pediatrics. 2) Doses above 2.5 mg daily in bipolar mania and 3 mg daily in schizophrenia provided no additional clinical benefit in studies and are associated with an increase incidence of adverse effects.</p> <p><i>Pregnancy:</i> No adequate and well controlled studies in pregnant women; crosses the placenta. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> Risperidone and its metabolite are present in human breast milk. Infants exposed to second generation antipsychotics via breast milk should be monitored weekly for the first month of exposure for symptoms, such as appetite changes, insomnia, irritability or lethargy.</p> |
|  | Bipolar mania: 10 and<br>older                                    | 0.5–6 mg daily   |  |
|  | Schizophrenia: 13 and<br>older                                    | 0.5–6 mg daily   |  |
| Mellaril<br><i>thioridazine†</i> (FGA) | Treatment-refractory<br>schizophrenia:<br>(Age not specified)     | 0.5–3 mg/kg/day  | <p><i>Additional Black Box Warning:</i> Dose-related prolongation of QTc interval may cause torsade de pointes-type arrhythmias and sudden death. Use restricted to schizophrenia patients who fail to show an acceptable response to standard antipsychotic drugs.</p> <p><i>Warnings and precautions:</i> FDA label does not include a specific age. It states medication can be used in pediatric patients with schizophrenia who are unresponsive to other agents.</p> <p><i>Pregnancy:</i> No teratogenic effects reported in product labeling. Jaundice or hyper-/hyporeflexia have been reported in newborn infants following maternal use of phenothiazines.</p>   |

| Drug Brand Name /<br>Generic Name                         | FDA Approved Age /<br>Indication          | Pediatric Dosage / Serum Level<br>When Applicable   | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|   |   |   | <i>Lactation:</i> It is not known whether thioridazine is excreted in human breast milk.  |
| Navane <i>thiothixene</i> <sup>†</sup><br>(FGA)           | Schizophrenia: 12 and older               | 6–60 mg daily   | <p><i>Warnings and precautions:</i> May cause CNS collapse, CNS depression and blood dyscrasias. Avoid use in patients with underlying QT prolongation or taking medicines that prolong the QT interval or cause polymorphic ventricular tachycardia.</p> <p><i>Pregnancy:</i> Safe use of thiothixene during pregnancy has not been established. Adverse events were observed in some animal reproduction studies.</p> <p><i>Lactation:</i> It is not known whether thiothixene is excreted in human breast milk.</p>  |
| Stelazine<br><i>trifluoperazine</i> <sup>†</sup><br>(FGA) | Behavioral disorders:<br>no age specified | 1–2 mg daily depending on the size of the child   | <p><i>Warnings and precautions:</i> May cause CNS collapse, CNS depression, blood dyscrasias, bone marrow depression and hepatic impairment.</p> <p><i>Pregnancy:</i> Adverse events have not been observed in animal reproduction studies, except when using doses that were also maternally toxic. Prolonged jaundice, extrapyramidal signs or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines.</p> <p><i>Lactation:</i> There is evidence that trifluoperazine is excreted in the milk of nursing mothers. Milk concentrations may be higher than those found in the maternal serum.</p> |
|   | Psychosis: 6 and older                    | 1–15 mg daily (some older children with severe symptoms may require, and be able to tolerate, higher dosages until 40 mg daily) |   |
| Geodon<br><i>ziprasidone</i> <sup>*</sup> (SGA)           | 18 and older                              | In June 2009, an FDA advisory panel advised that ziprasidone is effective in patients 10–17 years                               | <i>Warnings, precautions and administration:</i> 1) Doses should be administered with food. 2) Use can cause prolonged QTc interval.  |

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|                                   |                                  | of age for the treatment of mixed and manic episodes of BD but did not conclude that it was safe due to a large number of subjects lost in follow-up and ambiguity within QTc prolongation data. | <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women. Animal data suggests there may be risks.</p> <p><i>Lactation:</i> It is present in breast milk. There is limited data. Monitor infants exposed to ziprasidone via breast milk for excess sedation, irritability, poor feeding and EPS.</p> |

#### Antidepressant Medications (also used for anxiety disorders)

∞ †*Black Box Warning which applies to all antidepressants:* Increased risk of suicidal thinking and behaviors in children, adolescents and young adults (18–24) with MDD and other psychiatric disorders. Monitor for worsening and emergence of suicidal thoughts and behaviors.

‡ TCAs are not the drugs of choice for pediatric patients with depression; there is lack of high-quality data to support efficacy and safety. Monitoring of cardiac function is wise when TCAs are used in children.

∞ *Precautions which apply to all SSRI and all SNRI antidepressants:* Activation of mania/hypomania, discontinuation syndrome, increased risk of bleeding and use in combination with monoamine oxidase inhibitors (MAOIs).

∞ ‡ *Precautions which apply to all SNRIs:* Use in combination with MAOIs, activation of mania/hypomania, discontinuation syndrome, increased risk of bleeding.

*General precautions for MAOIs:* This class is usually reserved for patients who have failed other agents due to the strict dietary restrictions and side effects. Patients must avoid foods that are high in tyramine and alcohol. This medication should not be used if another MAOI has been previously prescribed. Serious, life-threatening side effects can occur if isocarboxazid is consumed before another MAOI has cleared from the body.

| Drug Brand Name /<br>Generic Name                           | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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| Elavil <i>amitriptyline</i> ‡<br>( <i>tricyclic [TCA]</i> ) | 12 and older                     | 50–200 mg daily                                   | <p><i>Warnings and precautions:</i> Controlled clinical trials have not shown TCAs to be superior to placebo for the treatment of depression in children and adolescents; not recommended as a first-line medication.</p> <p><i>Pregnancy:</i> Amitriptyline has been shown to cross the placenta. There have been a few reports of adverse events, including CNS effects, limb deformities or developmental delay in infants whose mothers took amitriptyline in pregnancy.</p> <p><i>Lactation:</i> Amitriptyline is excreted into breast milk. Because of the potential for serious adverse reactions in nursing infants from amitriptyline, a decision should be made whether to discontinue nursing or discontinue the drug.</p> |
| Asendin <i>amoxapine</i> ‡<br>( <i>TCA</i> )                | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> Most common adverse events are drowsiness, dry mouth, constipation and blurred vision.</p> <p><i>Pregnancy:</i> It is not known if amoxapine or its metabolite cross the human placenta. Reproductive studies in mice, rats and rabbits have found no teratogenicity, but embryotoxicity was observed in rats and rabbits given oral doses approximating the human dose.</p> <p><i>Lactation:</i> Amoxapine is excreted in human breast milk. Caution should be exercised when used in nursing women.</p>   |
| Wellbutrin,<br>Wellbutrin SR,                               | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) Contraindicated in those with seizure disorders or a current or prior diagnosis of bulimia</p>   |



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| Wellbutrin XL, Zyban<br><i>bupropion</i><br>(aminoketone class) |                                  |  | <p>or anorexia. 2) Can increase blood pressure. 3) Can cause false positive urine test results for amphetamines.</p> <p><i>Pregnancy:</i> Bupropion and its metabolites cross the placenta. An increased risk of congenital malformations has not been observed following maternal use of bupropion during pregnancy; however, data specific to cardiovascular malformations is inconsistent. The long-term effects on development and behavior have not been studied. If treatment for MDD is initiated for the first time during pregnancy, agents other than bupropion are preferred.</p> <p><i>Lactation:</i> Bupropion and its metabolites are excreted in human breast milk.</p> |
| Celexa <i>citalopram</i> *<br>(SSRI)                            | 18 and older                     | N/A  | <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women. Citalopram and its metabolites cross the human placenta. An increased risk of teratogenic effects, including cardiovascular defects, may be associated with maternal use of citalopram or other SSRIs; however, available information is conflicting.</p> <p><i>Lactation:</i> Citalopram is excreted in human breast milk. There have been reports of infants experiencing excessive sedation, decreased feeding and weight loss in association with breastfeeding. Caution should be exercised, and breastfeeding infants should be observed for side effects.</p>                                   |
| Anafranil<br><i>clomipramine</i> ‡ (TCA)                        | OCD: 10 and older                | 25–200 mg daily or<br>3 mg/kg/day, whichever is less | <p><i>Warnings and precautions:</i> 1) The most commonly observed adverse events are gastrointestinal complaints, including: dry mouth, constipation, nausea, dyspepsia, anorexia, tremor, dizziness and nervousness. 2) Seizure was</p>   |

| Drug Brand Name /<br>Generic Name              | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|  |                                  |   | <p>the most significant risk of clomipramine use in premarket evaluation. 3) Use with caution in patients with a history of seizures or predisposing factors like brain damage.</p> <p><i>Pregnancy:</i> No teratogenic effects were observed in mice and rat studies. Withdrawal symptoms, including jitteriness, tremor and seizures have been reported in neonates whose mothers have taken clomipramine until delivery. Clomipramine should only be used during pregnancy if the benefit outweighs the risk to the fetus.</p> <p><i>Lactation:</i> Clomipramine is excreted in human breast milk.</p>             |
| Pristiq<br><i>desvenlafaxine</i> ∞ ¥<br>(SNRI) | 18 and older                     | N/A   | <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women. Based on animal data, desvenlafaxine may cause fetal harm.</p> <p><i>Lactation:</i> Desvenlafaxine is excreted in human breast milk.</p>  |
| Sinequan <i>doxepin</i> ‡<br>(TCA)             | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> While the safety and effectiveness in the pediatric population have not been established, the product labeling specifically says use of doxepin in children under 12 years of age is not recommended because safe conditions for its use have not been established. Anyone considering the use of doxepin in a child or adolescent must balance the risk versus the benefit.</p> <p><i>Pregnancy:</i> Safety in pregnancy has not been established.</p> <p><i>Lactation:</i> Doxepin and metabolite are present in breast milk. Drowsiness, vomiting, poor feeding and muscle</p> |

| Drug Brand Name /<br>Generic Name               | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
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|   |                                  |   | hypotonia were noted in a breastfeeding infant following maternal use of doxepin.  |
| Cymbalta<br><i>duloxetine</i> ∞ ¥<br>(SNRI)     | GAD: 7 and older                 | 30–120 mg daily                                   | <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women; crosses the placenta. May impair platelet aggregation; the risk of postpartum hemorrhage may be increased when used within the month prior to delivery.</p> <p><i>Lactation:</i> Duloxetine is excreted in human breast milk.</p>  |
| Lexapro<br><i>escitalopram</i> * (SSRI)         | MDD: 12 and older                | 10–20 mg daily                                    | <p><i>Pregnancy:</i> No adequate and well controlled studies in pregnant women; crosses the placenta and is distributed into the amniotic fluid.</p> <p><i>Lactation:</i> Escitalopram is excreted in human breast milk. There have been reports of infants experiencing excessive sedation, decreased feeding and weight loss in association with breastfeeding. Caution should be exercised, and breastfeeding infants should be observed for side effects.</p>  |
| Spravato <i>esketamine</i><br>(NMDA antagonist) | 18 and older                     | N/A   | <p><i>Additional Black Box Warning:</i> 1) Has the potential to be abused and misused. 2) Patients are at risk for sedation after administration. Because of the risks of sedation, patients must be monitored for at least two hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting. 3) Patients are at risk for dissociative or perceptual changes after administration. Because of the risks of dissociation, patients must be monitored for at least two hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.</p> |

| Drug Brand Name /<br>Generic Name   | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable                    | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|                                     |                                  |  | <p><i>Warnings and precautions:</i> Must be given in conjunction with an oral antidepressant. Indicated for treatment-resistant depression and MDD with suicidality. Esketamine is not recommended in patients with severe hepatic impairment.</p> <p><i>Pregnancy:</i> Based on animal data, use of medications that block N-methyl-D-aspartate (NMDA) receptors and/or potentiate gamma-aminobutyric acid activity, may affect brain development. Females of reproductive potential should consider pregnancy planning and prevention during therapy.</p> <p><i>Lactation:</i> Esketamine is present in breast milk. Due to the potential for adverse events in a nursing infant, breastfeeding is not recommended.</p> |
| Prozac <i>fluoxetine*</i><br>(SSRI) | MDD: 8 and older                 | 10–20 mg daily   | <p><i>Pregnancy:</i> The effect on labor and delivery in humans is unknown. Prozac does cross the placenta so there is a possibility that it may have adverse effects on the newborn.</p> <p><i>Lactation:</i> Fluoxetine is excreted in human breast milk. Nursing while taking fluoxetine is not recommended.</p>   |
|                                     | OCD: 7 and older                 | 10–60 mg daily   |   |
| Luvox <i>fluvoxamine*</i><br>(SSRI) | OCD: 8 and older                 | 25–200 mg daily (kids over age 11 may need doses up to 300 mg daily) | <p><i>Warnings and precautions:</i> 1) Luvox CR is not indicated in children/adolescents. 2) May cause decreased appetite and weight loss, which have been observed with pediatric use. Regular monitoring of weight and growth is recommended.</p> <p><i>Pregnancy:</i> Crosses the placenta. If treatment for MDD is initiated for the first time in females planning a pregnancy, agents other than fluvoxamine are preferred.</p>   |

| Drug Brand Name /<br>Generic Name         | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable   | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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| Tofranil <i>imipramine</i> †<br>(TCA)     | Bedwetting: 6 and<br>older       | <p>Ages 6–11: 25–50 mg daily</p> <p>Ages 12 and older:<br/>25–75 mg daily</p> <p>Do not exceed the lesser of 2.5<br/>mg/kg/ day or 50 mg/day if<br/>younger than 12 or 75 mg/day if<br/>older than 12*</p> <p>*Give one hour before bedtime</p> | <p><i>Lactation:</i> Fluvoxamine is excreted in human breast milk.</p> <p><i>Warnings and precautions:</i> 1) The most common adverse effects in children with bedwetting are nervousness, sleep disorders, tiredness and mild stomach disturbances. The adverse events usually disappear during <i>continued</i> use or when the dosage is decreased. 2) Imipramine should only be used for short-term, add-on therapy. 3) Tofranil-PM is not indicated in children. It is generally recommended that Tofranil-PM should not be used in children because of the increased potential for acute overdose due to the high unit potency (75, 100, 125 and 150 mg). Anyone considering the use Tofranil-PM (imipramine pamoate) in a child or adolescent must balance the potential risks with the clinical need.</p> <p><i>Pregnancy:</i> Should not be used in women who are or might become pregnant as there have been clinical reports of congenital malformations associated with the use of imipramine.</p> <p><i>Lactation:</i> Present in human breast milk. Breastfeeding is not recommended by the manufacturer.</p> |
| Marplan<br><i>isocarboxazid</i><br>(MAOI) | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) The safety and effectiveness in pediatric populations has not been demonstrated but the product labeling specifically says Marplan is not recommended for use in patients under 16 years of age. 2) Because of adverse reactions and numerous drug interactions, Marplan is considered a second line agent in those who have failed other agents.</p>  |

| Drug Brand Name /<br>Generic Name              | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|  |                                  |   | <p><i>Pregnancy:</i> Safety in pregnancy has not been established. Animal reproduction studies have not been conducted.</p> <p><i>Lactation:</i> Levels of excretion into breast milk and effects on nursing infants is unknown.</p>  |
| Fetzima<br><i>levomilnacipran</i><br>(SNRI)    | 18 and older                     | N/A   | <p><i>Pregnancy:</i> Safety in pregnancy has not been established.</p> <p><i>Lactation:</i> It is not known if levomilnacipran is excreted in human breast milk. Studies have shown that it is present in the milk of lactating rats.</p>   |
| Ludiomil<br><i>maprotiline</i> ‡ (TCA)         | 18 and older                     | N/A   | <p><i>Pregnancy:</i> Safety in pregnancy has not been established.</p> <p><i>Lactation:</i> Maprotiline is excreted in human breast milk. Caution should be exercised when given to a nursing mother.</p>   |
| Remeron<br><i>mirtazapine</i><br>(tetracyclic) | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) Two trials in 258 pediatric patients with depression were conducted by the manufacturer and the data was not sufficient to support a claim for use. 2) Do not take if an MAOI was used within the past 14 days.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. There were no teratogenic effects seen in animal studies, though there is limited information. Crosses the placenta.</p> <p><i>Lactation:</i> Mirtazapine may be excreted into human breast milk so caution should be exercised when administered to nursing women.</p> |

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| Pamelor<br><i>nortriptyline</i> ‡ (TCA)       | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> Safety and effectiveness in the pediatric population has not been established. However, the package labeling did provide dosing for adolescents: 30–50 mg/day (no specific age was given for “adolescent”).</p> <p><i>Pregnancy:</i> Safe use during pregnancy has not been established. Crosses the placenta and can be detected in cord blood. Animal studies have yielded inconclusive results.</p> <p><i>Lactation:</i> Safe use during lactation has not been established. Present in breast milk.</p>  |
| Paxil, Paxil CR<br><i>paroxetine</i> * (SSRI) | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) Three placebo-controlled trials in 752 patients with depression were conducted with paroxetine and the data was not sufficient to support a claim for use in pediatric patients. 2) May cause nausea, somnolence, sweating, tremor, abnormal physical weakness or lack of energy, dry mouth, insomnia, sexual dysfunction, constipation, diarrhea and decreased appetite.</p> <p><i>Pregnancy:</i> Pregnancy Category D as a result of scientific evidence of positive teratogenic effects, particularly cardiovascular malformations. Paroxetine should be avoided in pregnancy if possible.</p> <p><i>Lactation:</i> Paroxetine is excreted in human breast milk. Caution should be used.</p> |
| Nardil <i>phenelzine</i><br>(MAOI)            | 18 and older                     | N/A   | <p><i>Pregnancy:</i> Safety in pregnancy has not been established. Adverse events have been observed in animal reproduction studies</p>  |

| Drug Brand Name /<br>Generic Name   | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|   |                                  |   | <i>Lactation:</i> Safety in lactation has not been established. It is not known if phenelzine is excreted in breast milk.   |
| Vivactil<br><i>protriptyline</i> ‡ (TCA)  | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> Safety and effectiveness in the pediatric population has not been established. However, the package labeling does provide dosing guidelines for adolescents: 5 mg three times daily, increase gradually if necessary (no specific age was given for adolescents and maximum doses were not given).</p> <p><i>Pregnancy:</i> Safety in pregnancy has not been established.</p> <p><i>Lactation:</i> Safety in lactation has not been established. It is not known if protriptyline is excreted in breast milk.</p> |
| Emsam (patch)<br><i>selegiline</i> (MAO-B<br>inhibitor /<br><i>phenethylamine</i><br>class) | 18 and older                     | N/A   | <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women.</p> <p><i>Lactation:</i> It is not known if selegiline is excreted in human breast milk. Studies have shown that it is present in the milk of lactating rats.</p>   |
| Zoloft <i>sertraline</i> *<br>(SSRI)  | OCD: 6 and older                 | 25–200 mg daily                                   | <p><i>Warnings and precautions:</i> 1) Solution contains 12% alcohol. 2) Studies in depression were not sufficient to support an indication for pediatric use.</p> <p><i>Pregnancy:</i> Overall, available published studies suggest no difference in major birth defect risk. No teratogenicity was observed in animal studies.</p> <p><i>Lactation:</i> Sertraline is excreted in human breast milk. In a published pooled analysis of 53 mother infant pairs,</p>  |



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|  |                                  |   | exclusively human milk fed, no adverse reactions in the breastfed infants were shown.   |
| Parnate<br><i>tranylcypromine</i><br>(MAOI)  | 18 and older                     | N/A   | <p><i>Pregnancy:</i> No adequate or controlled studies in pregnant women. Animal reproductive studies show that tranylcypromine passes through the placental barrier to the fetus of rats.</p> <p><i>Lactation:</i> Tranylcypromine is excreted in human breast milk.</p>   |
| Desyrel, Oleptro<br><i>trazodone (serotonin antagonist and reuptake inhibitor class)</i> | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> 1) Should not be used within 14 days of MAOI treatment. 2) Monitor for emergence of mania/hypomania. 3) May cause prolongation of the QT/QTc interval, increased risk of bleeding, priapism and possible hyponatremia.</p> <p><i>Pregnancy:</i> No adequate and well-controlled studies in pregnant women. Some rat and rabbit studies show adverse effects on the fetus at doses higher than the maximum human dose.</p> <p><i>Lactation:</i> Trazodone and its metabolites are found in the milk of lactating rats.</p> |
| Surmontil<br><i>trimipramine</i> ‡ (TCA)   | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> Though safety and effectiveness in the pediatric population has not been established, the FDA labeling provides dosing recommendations for adolescent patients of an initial dose of 50 mg daily with gradual increases up to 100 mg per day (no age range was given for adolescents).</p>  |

| Drug Brand Name /<br>Generic Name                             | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|   |                                  |   | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Trimipramine has shown evidence of embryotoxicity and/or increased incidence of major anomalies in rats or rabbits with doses beyond those approved in humans.</p> <p><i>Lactation:</i> Effects in the nursing infant are unknown.</p>   |
| Effexor, Effexor XR<br><i>venlafaxine</i> <sup>∞</sup> (SNRI) | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> According to the FDA labeling, two placebo-controlled trials in 766 pediatric patients with depression and two placebo-controlled trials in 793 pediatric patients with anxiety have been conducted with Effexor XR, and the data was not sufficient to support a claim for use in pediatric patients.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Rat and rabbit studies did not show teratogenicity. Effects on labor and delivery in humans are unknown. Crosses the placenta.</p> <p><i>Lactation:</i> Venlafaxine is excreted in human breast milk.</p> |
| Viibryd <i>vilazodone</i><br>(atypical<br>antidepressant)     | 18 and older                     | N/A   | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. There were no teratogenic effects seen when given to pregnant rats or rabbits.</p> <p><i>Lactation:</i> No data on the presence of vilazodone in human breast milk, the effects on breastfed infants or the effects of the drug on milk production. It is present in the milk of lactating rats.</p>   |
| Trintellix  | 18 and older                     | N/A   | <p><i>Warnings and precautions:</i> Product underwent a name change from Brintellix to Trintellix on 5/2/16 to decrease</p>   |

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| <i>Vortioxetine</i><br>(atypical<br>antidepressant –<br>serotonin<br>modulator) |                                     |   | <p>the risk of prescribing and dispensing errors due to name confusion with Brilinta, an antiplatelet medication.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, vortioxetine may cause fetal harm. Vortioxetine caused developmental delays when administered to pregnant rats and rabbits.</p> <p><i>Lactation:</i> It is not known whether vortioxetine is excreted in human breast milk. It is present in the milk of lactating rats.</p>   |
| <b>Combination Antipsychotic/Antidepressant Medications</b>                     |                                     |   |   |
| <i>Symbyax fluoxetine<br/>&amp; olanzapine</i>                                  | Bipolar depression:<br>10 and older | 3 mg/25 mg–12 mg/50 mg daily                      | <p><i>Black Box Warnings:</i> 1) Usage increased the risk of suicidal thinking and behaviors in children and adolescents with MDD and other psychiatric disorders. 2) Increased mortality in elderly patients with dementia-related psychosis treated with antipsychotics.</p> <p><i>Warnings and precautions:</i> 1) Avoid abrupt withdrawal. 2) Lower starting doses recommended for those with hepatic impairment, potential for slowed metabolism and those predisposed to hypotensive reactions.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Refer to individual agents in the combination product.</p> <p><i>Lactation:</i> Both fluoxetine and olanzapine are excreted in human breast milk. The mean dosage of olanzapine received by an infant at steady state is estimated to be</p> |

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|   |                                  |   | about 1.8% of the maternal dosage. Studies of fluoxetine have shown adverse effects in breast fed infants such as crying, sleep disturbances, vomiting and watery stools. It is recommended that women not breastfeed while taking Symbyax.   |
| <b>Mood Stabilizing and Anticonvulsant Medications</b>  |                                  |   |   |
| Black Box Warnings and warnings/precautions are specific to each medication. Please see chart for detailed information. Prior to prescribing, medical comorbidities, hepatic function, renal function, potential drug-drug interactions, alterations in protein binding and sensitivity to adverse events must be considered. |                                  |   |   |
| Equetro<br><i>carbamazepine<br/>extended-release<br/>capsules</i>   | 18 and older                     | N/A   | <i>Black Box Warning:</i> 1) Stevens-Johnson syndrome (Particularly among Asians), 2) Aplastic anemia, 3) Agranulocytosis.  |
| Tegretol, Tegretol XR, Carbatrol, Eptol<br><i>carbamazepine</i>   | Seizures: any age                | Under 6: 10–35 mg/kg/day<br><br>Ages 6–12: 20–1,000 mg daily<br><br>Ages 13–15: 400–1,000 mg daily<br><br>Ages 16 and older:<br>400–1,200 mg daily<br><br>**Recommended<br>therapeutic serum levels: 4–12<br>mcg/mL** | <i>Warnings and precautions:</i> 1) May cause neutropenia and hyponatremia. 2) Induces metabolism of itself and some other drugs. 3) May decrease efficacy of oral contraceptives. 4) Causes teratogenicity. 5) Don't use within 14 days of an MAOI. 6) Tegretol XR does not have dosing recommendations for patients under age 6.<br><br><i>Pregnancy:</i> May cause fetal harm when administered to pregnant women. Data suggest there may be an association with congenital malformations (including spina bifida), congenital anomalies and development disorders.<br><br><i>Lactation:</i> Carbamazepine and its metabolite are excreted into human breast milk. |
| Depakote, Depakote ER, Depakote   | Seizures<br>(monotherapy and     | 10–60 mg/kg/day   | <i>Black Box Warning:</i> 1) Hepatotoxicity, 2) Teratogenicity, 3) Pancreatitis.  |

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| Sprinkles <i>divalproex sodium</i><br>—<br>Depakene, Stavzar<br><i>valproic acid</i> | adjunctive): 10 and older        | Recommended therapeutic serum levels: 50–100 mcg/mL  | <p><i>Warnings, precautions and administration:</i> 1) May cause urea cycle disorders, multi-organ hypersensitivity reaction, thrombocytopenia, withdrawal seizures, suicidal ideation and polycystic ovaries. 2) Use may decrease the efficacy of birth control pills so alternative contraception should be used. 3) Depakote Sprinkles may be swallowed whole, or the contents of the capsule may be sprinkled on soft food. The food should be swallowed and not chewed.</p> <p><i>Pregnancy:</i> Can cause congenital malformations including neural tube defects and decreased IQ. Should not be used to treat women with epilepsy or BD who plan to become pregnant, due to risks of adverse fetal events.</p> <p><i>Lactation:</i> Excreted in human breast milk.</p> |
| Neurontin<br><i>gabapentin</i>   | Seizures (adjunct): 3 and older  | <p>Ages 3–11: 10–50 mg/kg/day</p> <p>Ages 12 and older:<br/>900–2,400 mg daily (Doses of 3,600 mg/day have also been administered to a small number of patients for short duration and have been well tolerated)</p> | <p><i>Warnings and precautions:</i> Dosage adjustments necessary for renal impairment or those undergoing hemodialysis.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm. Crosses the placenta.</p> <p><i>Lactation:</i> Gabapentin is excreted in human breast milk.</p>  |

| Drug Brand Name /<br>Generic Name                           | FDA Approved Age /<br>Indication           | Pediatric Dosage / Serum Level<br>When Applicable  | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
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| Lamictal, Lamictal XR<br><i>lamotrigine</i>                 | Epilepsy (adjunct): 2<br>and older         | <p>Ages 2–12: 0.15–15 mg/kg/day or maximum 300 mg daily (max dose is 400 mg daily if taking conflicting medications)</p> <p>12 and older: 25 mg every other day – 375 mg daily (max dose is 500 mg daily if taking conflicting medications)</p> <p>**Above doses may have to be increased or decreased for those patients taking concomitant valproate, carbamazepine, phenytoin, phenobarbital or primidone**</p> | <p><b>Black Box Warning:</b> Life threatening serious rashes including Stevens-Johnson syndrome. The rate of serious rash is greater in pediatric patients than in adults.</p> <p><b>Warnings and precautions:</b> 1) May cause vomiting, infection, fever, accidental injury, diarrhea, abdominal pain and tremor. Can also cause acute multi-organ failure, withdrawal seizures, blood dyscrasias, hypersensitivity and suicidal ideation. 2) Has been reported to cause false positive readings for phencyclidine (PCP) in some urine drug screens. 3) Some estrogen containing contraceptives have been shown to decrease serum concentrations of lamotrigine so dosage adjustments may be necessary. 4) Safety and efficacy for 10–17-year-olds with BD or 1–2-year-olds for adjunct therapy for seizures was not established.</p> <p><b>Pregnancy:</b> No adequate and well-controlled studies in pregnant women. In animal studies, lamotrigine was developmentally toxic at doses lower than those administered clinically.</p> <p><b>Lactation:</b> Lamotrigine is excreted in human breast milk. Apnea, drowsiness and poor sucking have been reported in milk fed infants exposed to lamotrigine.</p> |
|   | Epilepsy<br>(monotherapy): 16<br>and older | 16 and older: 200–500 mg daily   |  |
| Eskalith, Lithobid<br><i>lithium carbonate/<br/>citrate</i> | Bipolar mania: 12 and<br>older             | <p>300–2,400 mg daily</p> <p>Therapeutic serum levels: 0.6–1.2 mEq/L (toxic concentrations seen at levels greater than 1.5 mEq/L)</p>  | <p><b>Black Box Warning:</b> Toxicity above therapeutic serum levels.</p> <p><b>Warnings and precautions:</b> 1) May cause renal function impairment, polyuria, tremor, diarrhea, nausea and</p>   |

| Drug Brand Name /<br>Generic Name        | FDA Approved Age /<br>Indication          | Pediatric Dosage / Serum Level<br>When Applicable  |   | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
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|  |   |  |   | <p>hypothyroid. 2) Patients with significant renal or cardiovascular disease, severe debilitation, dehydration or sodium depletion are at higher risk of toxicity.</p> <p><i>Pregnancy:</i> Lithium may cause fetal harm when administered to a pregnant woman. Data from lithium birth registries suggest an increase in cardiac and other abnormalities. If possible, lithium should be withdrawn for at least the first trimester.</p> <p><i>Lactation:</i> Lithium is excreted in human breast milk. It is recommended to try to avoid breastfeeding while on lithium.</p>                |
| Trileptal<br><i>oxcarbazepine</i>        | Seizures<br>(monotherapy): 4 and<br>older | **Max<br>doses are<br>dependent<br>on<br>patient's<br>weight**   | 600–2,100 mg daily<br>(initiate at 8–10<br>mg/kg/day) | <p><i>Warnings and precautions:</i> 1) May cause hyponatremia and suicidal ideation. 2) May decrease the effectiveness of hormonal contraceptives. 3) Dose adjustments necessary in those with a creatinine clearance less than 30 ml/min.</p> <p><i>Pregnancy:</i> No adequate or well-controlled clinical studies in pregnant women. Closely related structurally to carbamazepine which is teratogenic in humans. Animal studies show the potential for harm to the fetus as well.</p> <p><i>Lactation:</i> Oxcarbazepine and its active metabolite are excreted in human breast milk.</p> |
|  | Seizures (adjunct): 2<br>and older        |  | 150–1,800 mg daily<br>(8–60 mg/kg/day)                |   |
| Topamax, Topamax<br>XR <i>topiramate</i> | Epilepsy<br>(monotherapy)                 | 10 and older: 25–400 mg daily (for<br>those younger than 10, there are<br>specific weight-based maxes) |   | <i>Warnings, precaution and administration:</i> 1) Because of the bitter taste, tablets should not be broken. 2) Decreases the efficacy of contraceptives and can cause increased   |

| Drug Brand Name / Generic Name           | FDA Approved Age / Indication | Pediatric Dosage / Serum Level When Applicable  | Black Box Warnings / Warnings and Precautions / Additional Information  |
|--|-------------------------------|---|---|
|  | Epilepsy (adjunctive)         | Ages 2–16: 25–9 mg/kg/day<br>(Recommended dose: 5–9 mg/kg/day)<br><br>17 and older: 25–400 mg daily       | breakthrough bleeding. 3) Capsules have to be swallowed whole and may not be sprinkled on food, crushed or chewed.<br><br><i>Pregnancy:</i> Topiramate can cause fetal harm when administered to a pregnant woman. Infants exposed to topiramate have an increased risk of cleft lip and/or palate. |
|  | Migraine: 12 and older        | 25–100 mg daily   |   |
| Trokendi XR, Qudexy XR <i>topiramate</i> | Epilepsy (monotherapy)        | Ages 6–9: 25–400 mg daily<br><br>Ages 10 and older: 50–400 mg daily                                       | <i>Lactation:</i> Topiramate is excreted in human breast milk. The effects of topiramate exposure on breastfed infants are unknown.   |
|  | Epilepsy (adjunctive)         | 25–9 mg/kg/day (Recommended dose: 5–9 mg/kg/day)<br><br>**Max doses are dependent on the child's weight** |   |

#### Anti-Anxiety Medications (Drugs below are *benzodiazepines* except buspirone)

*Classification of buspirone:* Anxiolytic psychoactive drug of the azapirones chemical class

*Warnings/precautions for all benzodiazepines:* 1) Avoid abrupt withdrawal. These agents should be used for a limited time period and discontinuation of these drugs requires tapering. 2) Benzodiazepines should be administered cautiously to patients with renal impairment or renal failure, hepatic disease or hepatic encephalopathy. 3) Liver and renal function should be monitored regularly during prolonged therapy. 4) Associated with serious adverse events when combined with opioids, benzodiazepines, alcohol or other drugs that depress the CNS.

|                         |                 |                 |  |
|-------------------------|-----------------|-----------------|--|
| Xanax <i>alprazolam</i> | 18 and older    | N/A             | <i>Pregnancy:</i> Crosses the placenta.<br><br><i>Lactation:</i> Present in breast milk. |
| Buspar <i>buspirone</i> | GAD: 6–17 years | 7.5–60 mg daily | <i>Pregnancy:</i> Adverse events have not been observed in animal reproduction studies.  |



| Drug Brand Name /<br>Generic Name  | FDA Approved Age /<br>Indication                     | Pediatric Dosage / Serum Level<br>When Applicable                                     | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|------------------------------------|--|---|--|
|                                    |  |   | <i>Lactation:</i> The extent of excretion of buspirone and its metabolites into human milk is not known. Buspirone and its metabolites are excreted in the milk of lactating rats.   |
| Librium<br><i>chlordiazepoxide</i> | Anxiety: 6 and older                                 | 10–30 mg daily  | <i>Pregnancy:</i> Chlordiazepoxide crosses the human placenta, and fetal serum concentrations are similar to those in the mother.<br><br><i>Lactation:</i> Excreted in breast milk.  |
| Klonopin<br><i>clonazepam</i>      | 18 and older   | N/A   | <i>Pregnancy:</i> Crosses the placenta.<br><br><i>Lactation:</i> Present in breast milk.   |
| Tranxene<br><i>clorazepate</i>     | Partial seizures: 9–12<br>years                      | 15–60 mg daily  | <i>Warnings and precautions:</i> Recommended to monitor blood count and liver function tests.<br><br><i>Pregnancy:</i> Metabolite crosses the placenta and is measurable in cord and amniotic fluid.<br><br><i>Lactation:</i> Present in breast milk and measurable in serum of breastfeeding infants.   |
| Valium<br><i>diazepam</i>          | Spasticity / muscle<br>spasms: 6 months<br>and older | 1–2.5 mg, 3–4 times daily initially;<br>increase gradually as needed and<br>tolerated | <i>Warnings and precautions:</i> According to the manufacturer, oral diazepam tablets are contraindicated in those with severe hepatic disease. In general, all forms of diazepam should be administered cautiously to patients with mild to moderate hepatic disease, cirrhosis, hepatic fibrosis and acute or chronic hepatitis because its elimination half-life can be prolonged, possibly resulting in toxicity.<br><br><i>Pregnancy:</i> Crosses the placenta. |

| Drug Brand Name /<br>Generic Name   | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable                        | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
|---|----------------------------------|--|---|
|   |                                  |  | <i>Lactation:</i> Present in breast milk.   |
| Ativan <i>lorazepam</i>   | Anxiety: 12 and older            | 0.25–2 mg/dose 2 or 3 times daily;<br>maximum dose: 2 mg/dose            | <i>Pregnancy:</i> Crosses the placenta.<br><br><i>Lactation:</i> Present in breast milk.  |
| Serax <i>oxazepam</i>   | 12 and older                     | 30–120 mg  | <i>Warnings and precautions:</i> Label states it is not indicated for under 6 years of age and absolute dosage for pediatric patients 6–12 years old is not established.<br><br><i>Pregnancy:</i> Crosses the placenta.<br><br><i>Lactation:</i> Present in breast milk.  |
| <b>ADHD Medications</b> (Drugs below are stimulants, except atomoxetine, clonidine and guanfacine)  |                                  |  |   |
| <p><i>Classification of non-stimulant drugs:</i> (1) Atomoxetine is a SNRI. (2) Clonidine and guanfacine are classified as alpha-2 receptor agonists.</p> <p><i>Black Box Warning for all stimulants:</i> Abuse potential. Risk of sudden death and serious cardiovascular events.</p> <p><i>Warnings/precautions for all stimulants:</i> May cause sudden death in those with pre-existing structural cardiac abnormalities or serious heart problems. May cause hypertension, psychiatric adverse events and possible growth suppression. Infants born to mothers who are dependent on amphetamines have an increased risk of premature delivery and low birth weight. These infants may experience symptoms of withdrawal as demonstrated by dysphoria, agitation and significant fatigue.</p> |                                  |  |   |
| Adzenys XR<br><i>amphetamine</i><br><i>extended release</i>   | ADHD: 6 and older                | Ages 6–12: 6.3–18.8 mg daily<br><br>Ages 13 and older: 6.3–12.5 mg daily | <i>Warnings and precautions:</i> 1) Adzenys XR is the first amphetamine extended release orally disintegrating tablet. 2) Do not substitute for other amphetamine products on a mg/mg basis.<br><br><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm. |

| Drug Brand Name /<br>Generic Name                      | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable  | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|--|----------------------------------|--|--|
|  |                                  |  | <i>Lactation:</i> Amphetamines are excreted in human breast milk.  |
| Dyanavel XR<br><i>amphetamine<br/>extended release</i> | ADHD: 6 and older                | 2.5–20 mg daily  | <p><i>Warnings, precautions and administration:</i> 1) Liquid solution that needs to be shaken prior to use. 2) Do not substitute for other amphetamine products on a mg/mg basis.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> Amphetamines are excreted in human breast milk.</p>   |
| Evekeo<br><i>amphetamine<br/>sulfate</i>               | ADHD: 3 and older                | 2.5–40 mg daily  | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> Amphetamines are excreted in human breast milk.</p>  |
|  | Narcolepsy: 6 and older          | 5–60 mg daily  |  |
|  | Exogenous obesity: 12 and older  | Up to 30 mg daily (take in divided doses) 30–60 minutes before meals                                 |  |
| Strattera<br><i>atomoxetine</i>                        | ADHD: 6 and older                | <p>Up to 70 kg: 0.5–1.4 mg/kg (lesser of 1.4 mg/kg or 100 mg)</p> <p>Over 70 kg: 40–100 mg daily</p> | <p><i>Black Box Warning:</i> Increased risk of suicidal ideation in children or adolescents.</p> <p><i>Warnings and precautions:</i> 1) Do not open capsule; must be swallowed whole. 2) May cause liver injury, adverse psychiatric events, increase blood pressure and heart rate, and serious cardiovascular events including sudden death, particularly in those with pre-existing structural cardiac abnormalities or serious heart problems.</p> |

| Drug Brand Name /<br>Generic Name        | FDA Approved Age /<br>Indication                  | Pediatric Dosage / Serum Level<br>When Applicable | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
|--|---|---|---|
|  |   |   | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. An agent other than atomoxetine is preferred for the treatment of ADHD in women planning a pregnancy.</p> <p><i>Lactation:</i> It is not known if atomoxetine is excreted in human breast milk. Atomoxetine and/or its metabolites are excreted in the breast milk of rats.</p>  |
| Kapvay <i>clonidine extended release</i> | ADHD (monotherapy or adjunct to stimulants): 6–17 | 0.1–0.4 mg daily                                  | <p><i>Warnings, precautions and administration:</i> 1) Can lower blood pressure and cause sedation. 2) Do not crush, chew or break tablets before swallowing. 3) Do not administer with high fat meals due to increased exposure. 4) May not see effects until 4–6 weeks. 5) Do not abruptly discontinue to avoid rebound hypertension. 6) Immediate release forms of clonidine (Catapres) are not FDA-approved for use in children.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Crosses the placenta; concentrations in the umbilical cord plasma are similar to those in the maternal serum and concentrations in the amniotic fluid may be four times those in the maternal serum.</p> <p><i>Lactation:</i> Clonidine is excreted in human breast milk.</p> |
| Focalin <i>dexmethylphenidate</i>        | ADHD: 6–17  | 5–20 mg daily                                     | <p><i>Warnings and precautions:</i> 1) Do not co-administer with MAOIs, or within 14 days following discontinuing a MAOI. 2) May induce psychotic or manic symptoms.</p> <p><i>Pregnancy:</i> Limited human data. Based on animal data, may cause fetal harm.</p>   |

| Drug Brand Name /<br>Generic Name  | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable            | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|--|----------------------------------|--|--|
|  |                                  |  | <i>Lactation:</i> It is not known whether dexamethylphenidate is excreted in human breast milk.  |
| Focalin XR<br><i>dexamethylphenidate<br/>extended release</i>                                | ADHD: 6 and older                | 5–30 mg daily  | <p><i>Warnings, precautions and administration:</i> 1) Do not co-administer with MAOIs, or within 14 days following discontinuing a MAOI. 2) May induce psychotic or manic symptoms. 3) Capsule contents can be sprinkled on applesauce and swallowed whole. 4) Capsule should not be crushed, chewed or divided.</p> <p><i>Pregnancy:</i> Limited human data. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> It is not known whether dexamethylphenidate is excreted in human breast milk. Dexamethylphenidate is the more active enantiomer of racemic methylphenidate, and methylphenidate is present in breast milk.</p> |
| Dexedrine,<br>ProCentra Oral<br>Solution, Zenzedi,<br>Dextrostat<br><i>dextroamphetamine</i> | ADHD: 3 and older                | 2.5–40 mg daily  | <i>Warnings and precautions:</i> Extended release Spansules can be used once a day when appropriate; tablets need to be given multiple times per day at intervals of 4–6 hours.  |
|  | Narcolepsy: 6 and older          | 5–60 mg daily  | <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> Amphetamines are excreted in human breast milk.</p>  |
| <i>Intuniv guanfacine<br/>extended release</i>   | ADHD (monotherapy and adjunct to | Ages 6–12: 1–4 mg daily (lesser of 0.12 mg/kg or 4 mg daily) | <i>Warnings, precautions and administration:</i> 1) Sedation, somnolence and fatigue are common and tend to decline over time. 2) Do not crush, chew or break tablets. 3) Do not   |

| Drug Brand Name /<br>Generic Name                 | FDA Approved Age /<br>Indication      | Pediatric Dosage / Serum Level<br>When Applicable                                    | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
|---|---------------------------------------|--|---|
|   | stimulants): 6 and<br>older           | Ages 13–17: 1–7 mg daily<br><br>**max dose depends on weight of<br>child**           | administer with high fat meal. 4) Do not discontinue<br>abruptly. 5) Dosage adjustments necessary if used with<br>Strong 3A4 inhibitors or inducers. 6) Immediate release<br>guanfacine/Tenex is only approved for hypertension in<br>patients 12 and older.<br><br><i>Pregnancy:</i> No adequate or well-controlled studies in<br>pregnant women.<br><i>Lactation:</i> It is not known whether guanfacine is excreted in<br>human breast milk; however, it is excreted in rat milk.  |
| Vyvanse<br><i>lisdexamfetamine<br/>dimesylate</i> | ADHD: 6–17                            | 30–70 mg daily   | <i>Warnings, precautions and administration:</i> 1) Dosage<br>adjustments needed for renal impairment. 2) Capsules can<br>be opened and mixed in yogurt, water or orange juice. The<br>contents should be mixed until completely dispersed and<br>the entire mixture should be consumed immediately.<br><br><i>Pregnancy:</i> Limited available data from published literature<br>and post marketing reports. Lisdexamfetamine is converted<br>to dextroamphetamine.<br><br><i>Lactation:</i> Amphetamines are present in human breast<br>milk. |
| Desoxyn<br><i>methamphetamine</i>                 | ADHD: 6 and older                     | 5–25 mg daily  | <i>Pregnancy:</i> No adequate or well-controlled studies in<br>pregnant women. Based on animal data, may cause fetal<br>harm.   |
|   | Obesity (short term):<br>12 and older | 5 mg thirty minutes before each<br>meal; treatment should not<br>exceed a few weeks. | <i>Lactation:</i> Amphetamines are excreted in human breast<br>milk.  |

| Drug Brand Name /<br>Generic Name  | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable   | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|--|----------------------------------|---|--|
| Adhansia XR,<br><i>methylphenidate</i>   | ADHD: 6 and older                | 25 mg daily initially; may titrate up<br>in increments 10–15 mg at least<br>every 5 days<br><br>Doses > 70 mg/day are associated<br>with increased side effects | <p><i>Administration:</i> May be swallowed whole or capsule<br/>opened and sprinkled onto 1 tablespoon of applesauce or<br/>yogurt and consumed within 10 minutes.</p> <p><i>Pregnancy:</i> There are limited published studies and a small<br/>case series that reported on the use of methylphenidate in<br/>pregnant women; however, the data are insufficient to<br/>inform any drug associated risks.</p> <p><i>Lactation:</i> Limited published literature reports that<br/>methylphenidate is present in human breast milk.</p>                   |
| Ritalin, Methylin<br><i>methylphenidate</i>  | ADHD: 6 and older                | 10–60 mg daily  | <p><i>Warnings, precautions and administration:</i> Methylin is a<br/>chewable tablet. It should be taken with at least eight<br/>ounces of water or other fluid to prevent choking.</p> <p><i>Pregnancy:</i> There are limited published studies and a small<br/>case series that reported on the use of methylphenidate in<br/>pregnant women; however, the data are insufficient to<br/>inform any drug associated risks.</p> <p><i>Lactation:</i> Limited published literature reports that<br/>methylphenidate is present in human breast milk.</p> |
| Methylin ER,<br>Metadate ER,<br>Ritalin SR, Aptensio<br>XR <i>methylphenidate</i><br><i>extended release</i> | ADHD: 6 and older                | 10–60 mg daily  | <p><i>Warnings, precautions and administration:</i> 1) Aptensio XR<br/>capsules can be opened, and the contents can be sprinkled<br/>over a spoonful of applesauce. This mixture should be<br/>consumed in its entirety. 2) Ritalin SR tablets must be<br/>swallowed whole and never crushed or chewed.</p> <p><i>Pregnancy:</i> There are limited published studies and small<br/>case series that report on the use of methylphenidate in</p>  |

| Drug Brand Name /<br>Generic Name   | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable                                       | Black Box Warnings / Warnings and Precautions /<br>Additional Information  |
|---|----------------------------------|---|--|
|   |                                  |   | <p>pregnant women; however, the data are insufficient to inform any drug associated risks.</p> <p><i>Lactation:</i> Limited published literature reports that methylphenidate is present in human breast milk.</p>   |
| Ritalin LA,<br>Metadate CD,<br>QuilliChew ER,<br>Quillivant XR<br><i>methylphenidate<br/>extended release</i> | ADHD: 6 and older                | 20–60 mg daily  | <p><i>Warnings, precautions and administration:</i> 1) Ritalin LA and Metadate CD capsules can be opened, and the contents can be sprinkled over a spoonful of applesauce. This mixture should be consumed in its entirety. 2) QuilliChew ER is the first once daily long-lasting methylphenidate chewable tablet. It can be broken in half. 3) Quillivant XR is the first once daily long-lasting methylphenidate liquid. It needs to be shaken vigorously for at least 10 seconds before use.</p> <p><i>Pregnancy:</i> There are limited published studies and a small case series that reported on the use of methylphenidate in pregnant women; however, the data is conflicting and insufficient to inform any drug associated risks.</p> <p><i>Lactation:</i> Methylphenidate is present in human breast milk.</p> |
| Concerta<br><i>methylphenidate<br/>long acting</i>  | ADHD: 6 and older                | Ages 6–12: 18–54 mg daily<br><br>Ages 13–17: 18–72 mg daily (not to exceed 2 mg/kg/day) | <p><i>Administration:</i> Should be swallowed whole and not chewed or crushed.</p> <p><i>Pregnancy:</i> There are limited published studies and a small case series that reported on the use of methylphenidate in pregnant women; however, the data are insufficient to inform any drug associated risks.</p>   |



| Drug Brand Name /<br>Generic Name                           | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable                  | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
|---|----------------------------------|--|---|
|   |                                  |  | <i>Lactation:</i> Limited published literature reports that methylphenidate is present in human breast milk.  |
| Daytrana<br><i>methylphenidate<br/>patch</i>                | ADHD: 6–17                       | 10–30 mg daily   | <p><i>Administration:</i> Should be applied to the hip area two hours before an effect is needed and removed nine hours after application (alternate hips).</p> <p><i>Pregnancy:</i> There are limited published studies and a small case series that reported on the use of methylphenidate in pregnant women; however, the data are insufficient to inform any drug associated risks.</p> <p><i>Lactation:</i> Limited published literature reports that methylphenidate is present in human breast milk.</p> |
| Adderall<br><i>Mixed amphetamine<br/>salts</i>              | ADHD: 3 and older                | 2.5–40 mg daily  | <i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm.   |
|   | Narcolepsy: 6 and older          | 5–60 mg daily  | <i>Lactation:</i> Amphetamines are excreted in human breast milk.   |
| Adderall XR <i>Mixed amphetamine salts extended release</i> | ADHD: 6 and older                | Ages 6–12: 10–30 mg daily<br><br>Ages 13 and older: 10–20 mg daily | <p><i>Administration:</i> Capsule may be opened and sprinkled on soft foods.</p> <p><i>Pregnancy:</i> No adequate or well-controlled studies in pregnant women. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> Amphetamines are excreted in human breast milk.</p>  |

| Drug Brand Name /<br>Generic Name  | FDA Approved Age /<br>Indication | Pediatric Dosage / Serum Level<br>When Applicable  | Black Box Warnings / Warnings and Precautions /<br>Additional Information   |
|--|----------------------------------|--|---|
| Azstarys,<br><i>Serdexmethylphenidate</i> /<br><i>dexmethylphenidate</i> | ADHD: 6–12                       | Initial: 39.2 mg/7.8 mg<br><br>After one week, can increase 52.3 mg/10.4 mg OR decrease to 26.1 mg/ 5.2 mg | <p><i>Warnings, precautions and administration:</i> 1) Do not co-administer with MAOIs, or within 14 days following discontinuing a MAOI. 2) May induce psychotic or manic symptoms. 3) Capsule may be taken whole or opened and sprinkled over applesauce or added to water.</p> <p><i>Pregnancy:</i> Limited human data. Based on animal data, may cause fetal harm.</p> <p><i>Lactation:</i> It is unknown whether Serdexmethylphenidate/dexmethylphenidate is excreted in human breast milk. Methylphenidate is present in human breast milk.</p>   |
|  | ADHD: 13–17                      | Initial: 39.2 mg/7.8 mg<br><br>After one week, can increase 52.3 mg/ 10.4 mg                               |   |
| Qelbree, <i>Viloxazine</i><br><br>(Not a stimulant medication)           | ADHD: 6-11                       | Initial: 100 mg daily<br><br>May increase in weekly 100 mg increments                                      | <p><i>Black Box Warning:</i> Increased risk of suicidal thoughts and behaviors.</p> <p><i>Warnings, precautions and administration:</i> 1) Do not co-administer with MAOIs, or within 14 days following discontinuing a MAOI. 2) Coadministration of CYP1A2 substrates may increase the risk of adverse events. 3) Capsule may be taken with or without food or sprinkled over a teaspoon of applesauce. 4) May induce mania or mixed episode in patients with bipolar. 5) Suicidal thoughts and behaviors were reported.</p> <p><i>Pregnancy:</i> Based on animal studies, maternal harm may occur.</p> <p><i>Lactation:</i> It is unknown if viloxazine is excreted in human breast milk.</p> |
|  | ADHD: 12–17                      | Initial: 200 mg daily<br><br>May increase in weekly 200 mg increments<br><br>Max 400 mg a day              |   |

*Sources: (Larsen et al., 2015; Lexicomp, n.d.; NIMH, n.d.; Micromedex, n.d.; Schatzberg & DeBattista, 2019; Pacchiarotti et al., 2019; The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission, 2019; Uguz, 2016)*

# Psychotropic drugs: Side effects and teratogenic risks

| Class of Drugs             | Typical Side Effects  | Possible Teratogenic Risk   | Legacy Pregnancy Risk Category <sup>1</sup>                                  |
|----------------------------|---|---|--|
| Antipsychotic medications  | <ul style="list-style-type: none"> <li>• Akathisia and dystonic reactions are seen in children treated with SGAs, but risk of tardive dyskinesia is small compared to FGAs.</li> <li>• Weight gain is a significant problem with SGAs. Other side effects: constipation, dry mouth and dizziness.</li> <li>• Sedation/cognitive blunting may occur with FGAs and SGAs.</li> <li>• Adolescent males at much greater risk for dystonic reactions than adults.</li> <li>• Significant drop in neutrophils and increased risk of seizures with clozapine (should be used as treatment of last resort).</li> </ul> | FGAs: Rare anomalies, fetal jaundice, fetal anticholinergic effects at birth.                                   | C  |
|                            |   | SGAs: Gestational diabetes, large birthweight.  | BC   |
| Antidepressant medications | TCAs: May cause significant slowing of cardiac conduction (PR interval over 0.20 msec, QRS interval over 0.12 msec); may require lowering dose. Cardiac long QT syndrome may be mechanism responsible for four cases of reported sudden death in children. Other effects: Dry mouth, urinary retention, sedation, constipation, weight gain and hypotension.  | TCAs: Fetal tachycardia, fetal withdrawal, fetal anticholinergic effects, urinary retention, bowel obstruction. | D-<br>amitriptyline,<br>Imipramine,<br>nortriptyline<br>C- (other<br>TCAs) / |

<sup>1</sup> In 2015, the FDA new labeling requirements, “Pregnancy and Lactation Labeling Rule” (PLLR), went into effect, effectively phasing out the previous pregnancy risk categories (A, B, C, D, and X; descriptions below), which made risk-to-benefit assessments challenging. The previous pregnancy risk categories were replaced with a standardized summary of available clinical evidence, supporting data and an explanation of risks to provide more detailed information regarding the safety and efficacy of medications in pregnancy and lactation and enable better evidence-based decision making. Pregnancy risk categories are included in this chart for reference, but please note the FDA has moved away from utilizing these. (Pernia & DeMaagd, 2016)

A: controlled studies show no risk to humans.

B: No evidence of risk in humans, but adequate human studies may not have been performed.

C: Risk cannot be ruled out.

D: Positive evidence or risk to humans; risk may be outweighed by potential benefit.

X: Contraindicated in pregnancy.

| Class of Drugs                                  | Typical Side Effects   | Possible Teratogenic Risk   | Legacy Pregnancy Risk Category <sup>1</sup> |
|---|--|---|---|
|   |  |   | B-maprotiline                               |
|   | In addition to strict dietary restrictions with MAOIs: Daytime sleepiness, dizziness, lightheadedness, low blood pressure, difficulty urinating, dry mouth, altered sense of taste, nervousness, muscle aches, insomnia and weight gain.   | MAOIs: Rare fetal malformations: rarely used in pregnancy due to hypertension.  | C   |
|   | <ul style="list-style-type: none"> <li>Safety/side effect profiles of SSRIs are superior to those of TCAs. Other SSRI side effects: Insomnia, sedation, appetite changes (up or down), nausea, dry mouth, headache, sexual dysfunction.</li> <li>Treatment-emergent akathisia from SSRIs may be more evident in pediatric depression associated with BD and greater suicide risk.</li> </ul> | SSRIs: Perinatal and cardiovascular complications, spontaneous abortions. Potential premature delivery and neonatal PPHN. | C/D (paroxetine)                            |
|   | Side effects and other concerns with SNRIs: nausea, insomnia, sedation, sexual dysfunction, sweating, hypertension and discontinuation syndrome.   | SNRIs: Potential premature delivery. Clinical outcome data sparse compared to SSRIs or TCAs.                              | C   |
|   | Bupropion (aminoketone class) common side effects: headache, agitation, restless insomnia, weight loss, anorexia, sweating, tremor and hypertension.   | Bupropion: Risks unknown, but not recommended over SSRIs in pregnancy.  | C   |
| Mood stabilizing and anticonvulsant medications | Lithium common reactions: tremor, polyuria, polydipsia, weight gain, diarrhea, vomiting, drowsiness, cognitive impairment, muscle weakness, impaired coordination, anorexia, nausea, blurred vision, xerostomia, fatigue, alopecia, reversible leukocytosis, acne and edema.   | Lithium: Associated with increase in birth defects including cardiac anomalies (esp. Ebstein's                            | D   |

| Class of Drugs           | Typical Side Effects   | Possible Teratogenic Risk   | Legacy Pregnancy Risk Category <sup>1</sup> |
|--------------------------|--|---|---|
|                          |  | anomaly) and behavioral effects.  |   |
|                          | Valproate: Children younger than 2 years are at greatest risk for hepatotoxicity. Common reactions: headache, nausea/vomiting, loss of muscle strength, somnolence, thrombocytopenia, dyspepsia, dizziness, diarrhea, abdominal pain and tremor.   | Valproate: Neural tube defects (i.e., rate 6–20% ); high rates of mental retardation and lower IQ measures.   | D   |
|                          | Carbamazepine: May cause dizziness, drowsiness, unsteadiness, impaired coordination, nausea/vomiting, blurred vision, nystagmus, rash and confusion.   | Carbamazepine: Neural tube defects, minor anomalies.  | D   |
|                          | Oxcarbazepine: May cause dizziness, somnolence, diplopia, visual changes, fatigue, headache, nausea, vomiting and ataxia.  | Oxcarbazepine: Unknown.   | C   |
|                          | Lamotrigine: Children are at greater risk for rash than adults. May cause nausea, vomiting, dizziness, vertigo, visual disturbance, somnolence, ataxy, pruritus/rash, headache, pharyngitis, rhinitis, diarrhea, fever and loss of muscle strength.  | Lamotrigine: Unknown but there appears to be a high rate of cleft lip and palate (i.e., 4–9/1,000).   | C   |
|                          | Gabapentin: May cause dizziness, somnolence, ataxia, fatigue, peripheral edema, nystagmus, nausea, vomiting and viral infection.   | Gabapentin / pregabalin: Unknown.   | C   |
|                          | Pregabalin: May cause dizziness, somnolence, xerostomia, peripheral edema, blurred vision, weight gain, abnormal thinking, constipation, impaired coordination, pain and decreased platelets.  |   | C   |
| Anti-anxiety medications | <ul style="list-style-type: none"> <li>• Benzodiazepines (BZDs): If used for daytime anxiety, can increase activity and produce or aggravate behavior disorders (particularly in ADHD). Drugs cause tolerance and physical/psychological dependence. May cause somnambulism and amnesia. Other side effects include psychomotor retardation, memory impairment, paradoxical disinhibition (i.e., increased excitement, irritability, aggression, hostility and impulsivity), depression and emotional blunting.</li> </ul> | <p>BZDs: “Floppy baby,” withdrawal, increased risk of cleft lip or palate.</p> <p>Hypnotic BZDs: Decreased intrauterine growth</p> <p>Buspiron: Unknown</p> | D/X (hypnotic BZDs)                         |

| Class of Drugs | Typical Side Effects   | Possible Teratogenic Risk | Legacy Pregnancy Risk Category <sup>1</sup> |
|----------------|--|---------------------------|---|
|                | <ul style="list-style-type: none"> <li>• Sedative antihistamines may have some antianxiety or hypnotic ability. Prolonged used of these agents may lead to anticholinergic side effects and cognitive impairment.</li> <li>• Buspirone can cause drowsiness, dizziness, impaired concentration, nausea and headache. Depression, hostility and akathisia, dystonia, tardive dyskinesia and EPS can occur.</li> </ul> |                           |   |

Sources: (Hilt, 2012; Lexicomp, n.d.; Micromedex, n.d.; Schatzberg & DeBattista, 2019; Yonkers et al., 2009)

# Recommended clinical monitoring of children and adolescents for select psychotropic drugs

| Class of Drugs                       | Monitoring Recommendation   | Frequency Suggestion  |
|--------------------------------------|---|---|
| Atypical antipsychotic medications   | <ol style="list-style-type: none"> <li>1. Height and weight</li> <li>2. Labs: Fasting blood sugar, fasting triglyceride/cholesterol</li> <li>3. Screen for dyskinesia movements</li> <li>4. Labs: Complete blood count (CBC) with differential values (diff)</li> <li>5. Blood pressure/pulse</li> <li>6. Cardiac history</li> <li>7. Determine if treatment responsive</li> </ol>  | <ol style="list-style-type: none"> <li>1. At baseline and at each follow-up visit (at least every six months)</li> <li>2. At least every six months</li> <li>3. At least every six months</li> <li>4. Once, two to three months after start of drug</li> <li>5. At least once after start of drug</li> <li>6. At baseline and obtain ECG if in doubt about risk from a mild QT increase</li> <li>7. Repeat disorder-specific rating scales(s) until remission is achieved. Increase at four-to-six-week intervals if insufficient drug benefit</li> </ol>   |
| Antidepressant (SSRI) medications    | <ol style="list-style-type: none"> <li>1. Blood pressure monitoring</li> <li>2. Hepatic function testing</li> <li>3. Assess for suicidal thinking/behaviors, clinical worsening or other changes in behaviors</li> <li>4. Inquire about activation symptoms</li> <li>5. Inquire about bleeding/bruising</li> <li>6. Measure height and weight</li> <li>7. Determine treatment response</li> <li>8. Pregnancy testing</li> </ol> | <ol style="list-style-type: none"> <li>1. Prior to treatment and with dose titration</li> <li>2. Baseline and as clinically indicated</li> <li>3. Ongoing—usually around week two, weeks four to six and other visits</li> <li>4. Screen for new irritability or agitation around week two and weeks four to six</li> <li>5. At least once after treatment begins</li> <li>6. At baseline and each F/U visit, at least every six months</li> <li>7. Repeat disorder-specific rating scales(s) until remission is achieved. Increase at four-to-six-week intervals if insufficient drug benefit</li> <li>8. As clinically indicated</li> </ol> |
| Antidepressant (SNRI) medications    | <ol style="list-style-type: none"> <li>1. Blood pressure</li> <li>2. Hepatic function</li> <li>3. Monitor for emergence of suicidal ideation or behavior</li> <li>4. Pregnancy testing</li> </ol>   | <ol style="list-style-type: none"> <li>1. Prior to initiating treatment, during dosage titration and as clinically indicated</li> <li>2. At baseline and as clinically indicated</li> <li>3. Ongoing—usually around week two, weeks four to six and other visits</li> <li>4. As clinically indicated</li> </ol>   |
| Tricyclic antidepressant medications | <ol style="list-style-type: none"> <li>1. ECGs</li> <li>2. Obtain outside consultation</li> </ol>   | <ol style="list-style-type: none"> <li>1. Prior to starting TCA therapy, when dose exceeds 3 mg/kg and then every two weeks if dose is being increased</li> <li>2. When prescribing doses &gt; 5 mg/kg</li> </ol>   |



|   |  |  |
|---|--|--|
|   | <ol style="list-style-type: none"> <li>3. Lower dosage with significant slowing of cardiac conduction</li> <li>4. Monitor for emergence of suicidal ideation or behavior</li> </ol>  | <ol style="list-style-type: none"> <li>3. In cases with ECG findings: PR interval over 0.20 msec, QRS interval over 0.12 msec</li> <li>4. Ongoing—usually around week two, weeks four to six and other visits</li> </ol>   |
| Stimulant medications                           | <ol style="list-style-type: none"> <li>1. Height and weight</li> <li>2. Blood pressure and pulse</li> <li>3. Cardiac history</li> <li>4. Refill monitoring</li> <li>5. CBC with diff</li> <li>6. Determine if treatment response</li> </ol>  | <ol style="list-style-type: none"> <li>1. At baseline and each F/U visit, at least every six months</li> <li>2. At baseline and at least once on a given dose of medication</li> <li>3. At baseline to determine if any risks from adrenergic stimulation</li> <li>4. Track date of each refill to identify signs of drug diversion</li> <li>5. For methylphenidate only, at least once every six months</li> <li>6. Repeat ADHD-specific rating scale(s) until remission is achieved. Increase at two to four weeks if insufficient response</li> </ol> |
| Mood stabilizing and anticonvulsant medications | <ol style="list-style-type: none"> <li>1. Lithium: (a) Chemistry Panel, CBC with platelets, serum creatinine, thyroid function tests, pregnancy test, ECG. (b) Once dose is stable—lithium levels, renal and thyroid function and urinalysis.</li> <li>2. Divalproex sodium: (a) Chemistry Panel, CBC with platelets, liver function tests, pregnancy test. (b) Serum drug levels, hepatic and hematological indices.</li> <li>3. Carbamazepine: (a) CBC, electrolytes and liver function tests. (b) Therapeutic drug levels.</li> </ol> | <ol style="list-style-type: none"> <li>1. Baseline monitoring (b) every three to six months</li> <li>2. Baseline monitoring (b) every three to six months</li> <li>3. Baseline monitoring (b) Routine monitoring in growing children to check for autoinduction of carbamazepine— usually occurring after one week and/or dosage changes</li> </ol>  |

*Sources: (Hilt, 2012; Kudriakova et al., 1992; Lexicomp, n.d., McClellan et al., 2007; Micromedex, n.d., Schatzberg & DeBattista, 2019; The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission, 2019)*

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