At-A-Glance: Psychotropic Drug Information for Children and Adolescents

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
Combination Antipsychotic/Antidepressant			
Symbyax *fluoxetine & olanzapine*	Bipolar depression: 10 and older	3mg/25 mg–12mg/50 mg daily	*Black Box Warnings:* 1) Usage increased the risk of suicidal thinking and behaviors in children and adolescents with major depressive disorder and other psychiatric disorders. 2) Increased mortality in elderly patients with dementia-related psychosis. *Warnings and precautions:* 1) Avoid abrupt withdrawal. 2) Lower starting doses recommended for those with hepatic impairment, potential for slowed metabolism, and those predisposed to hypotensive reactions. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* Both fluoxetine and olanzapine are excreted in human breast milk. 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.
Antipsychotic Medications			
Black Box Warning for all atypical /second generation antipsychotics (SGA): Increased mortality in elderly patients with dementia-related psychosis **Precautions which apply to all atypical or second generation antipsychotics (SGA):* Neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia, diabetes, weight gain, akathisa, and dyslipidemia. As such, patients on these drugs should have their weight, blood pressure, glucose, and lipids checked before starting these medications and rechecked at 12 weeks, one year, and at least once annually after that. *†Precautions which apply to all typical or first generation antipsychotics (FGA):* Extrapyramidal symptom, tardive dyskinesia *Precautions which apply to all antipsychotics:* neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms			
Abilify *aripiprazole* (SGA)*	Irritability associated with autistic disorder: 6 and older Tourette's Disorder: 6 and older Bipolar I disorder, manic or mixed episodes, monotherapy or as an adjunct to lithium: 10 and older Schizophrenia: 13 and older	2–15 mg daily (irritability with autistic disorder) < 50 kg: 2–10 mg daily > 50 Kg: 2–20 mg daily (Tourette's) 2–30 mg daily (Bipolar I, manic or mixed, monotherapy or adjunct to lithium) 2–30 mg daily (schizophrenia)	*Additional Black Box Warning:* 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. *Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. In animal studies, aripiprazole demonstrated developmental toxicity, included possible teratogenic effects. *Lactation:* Aripiprazole is excreted in human breast milk.

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Antipsychotic Medications *continued*			
Saphris *asenapine* (SGA)*	Bipolar mania: 10–17	2.5–10 mg twice daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* It is not known if asenapine is excreted in human breast milk. It is excreted in the milk of rats during lactation.
Rexulti *brexpiprazole (SGA)*	18 and older	N/A	*Additional Black Box Warnings:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. No adverse developmental or teratogenic effects were seen in animal studies. *Lactation:* It is not known if brexpiprazole and its metabolites are excreted in human breast milk. It is excreted in
Vraylar *cariprazine (SGA)*	18 and older	N/A	*Pregnancy:* No adequate or well controlled studies in pregnant women. No teratogenic effects were seen in animal studies but there were reports of malformations and developmental toxicities in rat pups. *Lactation:* It is not known if cariprazine is excreted in human breast milk. It is excreted in the milk of rats during lactation.

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Antipsychotic Medications *continued*			
Thorazine *chlorpromazine† (FGA)*	Severe Behavioral Problems marked by combativeness 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 (impulsivity, difficulty sustaining attention, aggressivity, mood lability, and poor frustration tolerance: 6 mos and older Nausea and Vomiting: 6 mos and older Presurgical Apprehension: 6 months and older	Outpatients: 0.25 mg/lb body weight every 4–6 hours as needed Hospitalized patients: start with low doses and increase gradually. In severe behavior disorders, higher dosages may be necessary; 50–100 mg daily. 200 mg daily in older children. (severe behavioral problems **There is little evidence that behavior improvement in severely disturbed mentally retarded patients is further enhanced by doses beyond 500 mg per day** (Severe behavioral problems) 0.25 mg/lb body weight (adjust dosage and frequency based on severity of symptoms and response of the patient) (Nausea and vomiting) 0.25mg/lb 2–3 hours before operation (presurgical apprehension)	*Warnings and precautions:* 1) May alter cardiac conduction and cause sedation, Neuroleptic Malignant Syndrome, and weight gain. 2) Use caution with renal disease, seizure disorders, respiratory disease, and in acute illness. 3) Should generally not be used in pediatric patients under 6 months of age except where potentially lifesaving. *Pregnancy:* 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. *Lactation:* Chlorpromazine is excreted in human breast milk.
Clozaril *clozapine* (SGA)*	18 and older	N/A	*Black Box Warnings:* 1) Agranulocytosis 2) Seizures 3) Myocarditis and cardiomyopathy 4) Adverse cardiovascular and respiratory effects. *Pregnancy:* No adequate or well controlled studies in pregnant women. Animal studies revealed no evidence of impaired fertility or harm to the fetus. *Lactation:* Clozapine is present in human breast milk.
Haldol *haloperidol† (FGA)*	Schizophrenia: 3 and older Tourette's Syndrome, and Disruptive Behavior Disorder and ADHD: 3 and older	0.05 -0.15 mg/kg/day (schizophrenia) 0.05 – 0.075 mg/kg/day (Tourette's and ADHD)	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. Animal studies show haloperidol may harm fetus. *Lactation:* Infants should not be nursed while on haloperidol

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Antipsychotic Medications *continued*			
Fanapt *iloperidone* (SGA)*	18 and older	N/A	*Warnings and precautions:* 1) May cause prolonged QTc interval and priapism. 2) Not recommended for patients with severe liver impairment *Pregnancy:* The limited available data in pregnant women is not sufficient to inform a drug associated risk for major defects and miscarriage. *Lactation:* It is not known if iloperidone and its metabolites are excreted in human milk. It is excreted in the milk of rats during lactation.
Loxitane *loxapine† (FGA)*	18 and older	N/A	*Warnings and precautions:* 1) Should be used in extreme caution in patients with a history of convulsive disorders since it lowers seizure threshold. 2) Use in caution in those with cardiovascular disease. *Pregnancy:* Safe use in pregnancy has not been established. *Lactation:* The extent of excretion in human milk is not known, however, loxapine and its metabolites have been shown to be transported into the milk of lactating dogs. Administration to nursing women should be avoided if clinically possible.
Adasuve *loxapine† (FGA)*	18 and older	N/A	*Additional Black Box Warning:* 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 *Warnings and precautions:* 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 *Pregnancy:* Based on animal data, may cause fetal harm. *Lactation:* 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.
Latuda *lurasidone (SGA)*	Schizophrenia: 13 and older	40–80 mg daily	*Additional Black Box Warnings:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. No adverse developmental or teratogenic effects were seen in animal studies. *Lactation:* 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.

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Antipsychotic Medications *continued*			
Moban *molindone† (FGA)*	Schizophrenia: 12 and older	15 mg–225 mg daily depending on the severity of the disorder and response to treatment	*Warnings and precautions:* Drowsiness is the most frequently occurring adverse effect. *Pregnancy:* Animal reproductive studies have not demonstrated a teratogenic potential. The benefits must be weighed against the unknown risks to the fetus if used in pregnant patients. *Lactation:* It is not known if molindone is excreted in human breast milk.
Zyprexa *olanzapine* (SGA)*	Schizophrenia and Bipolar I Disorder, mania or mixed episodes: 13 and older	2.5–20 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate and well-controlled studies in pregnant women. *Lactation:* Olanzapine is excreted in human breast milk.
Invega *paliperidone* (SGA)*	Schizophrenia: 12 and older	< 51kg: 3–6 mg daily ≥ 51kg: 3–12 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. In animal reproduction studies, there were no increases in fetal abnormalities. *Lactation:* Paliperidone is excreted in human breast milk.
Trilafon *perphenazine† (FGA)*	Schizophrenia: 12 and older	Adult dosages below. See additional information note in the next box. Oral: 2–64 mg daily (12–24 mg is average daily dose) Injection: 5 mg per dose. Injection can be repeated every 6 hours not to exceed 15 mg in ambulatory patients or 30 mg in hospitalized patients per day	*Warnings and precautions:* 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. *Pregnancy:* Safe use in pregnancy has not been established. *Lactation:* Safe use during lactation has not been established.
Orap *pimozide† (FGA)*	Tourette's Disorder: 12 and older	≥ 12 yrs: 0.05 mg/kg–0.2 mg/kg; not to exceed 10 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* It is not known whether pimozide is excreted in human breast milk.

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Antipsychotic Medications *continued*			
Seroquel *quetiapine* (SGA)*	Bipolar I Disorder: 10 and older Schizophrenia: 13 and older	25–600 mg daily 25–800 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* It is not known whether pimozide is excreted in human breast milk.
Seroquel XR *quetiapine* (SGA)*	Bipolar I Disorder: 10 and older Schizophrenia: 13 and older	50–600 mg daily 50–800 mg daily	*Additional Black Box Warning:* Increased risk of suicidal thoughts and behaviors in children, adolescents, and young adults taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors. *Warnings and precautions:* May cause somnolence, dizziness, fatigue, increased appetite, nausea, vomiting, dry mouth, tachycardia, and weight gain. *Pregnancy:* Limited human data. Based on animal data, may cause fetal harm. *Lactation:* Quetiapine is excreted in human breast milk.
Risperdal *risperidone* (SGA)*	Irritability associated with autistic disorder: 5 and older Bipolar mania: 10 and older Schizophrenia: 13 and older	<20 kg: 0.25–3 mg daily ≥20 kg: 0.5–3 mg daily 0.5–6 mg daily 0.5–6 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate and well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Risperidone and its metabolite are present in human breast milk.
Mellaril *thioridazine† (FGA)*	Treatment Refractory Schizophrenia: (age not specified)	0.5–3mg/kg/day	*Additional Black Box Warning:* Dose-related prolongation of QTc interval may cause torsade de pointes-type arrhythmias and sudden death. Use restricted to schizophrenia resistant to standard antipsychotic drugs. *Warnings and precautions:* 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. *Pregnancy:* No teratogenic effects reported in product labeling. *Lactation:* It is not known whether thioridazine is excreted in human breast milk.

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Antipsychotic Medications *continued*			
Navane *thiothixene†(FGA)*	Schizophrenia: 12 and older	6–60 mg daily	*Warnings and precautions:* May cause CNS collapse, CNS depression, blood dyscrasias. *Pregnancy:* Safe use of thiothixene during pregnancy has not been established. *Lactation:* It is not whether thiothixene is excreted in human breast milk.
Stelazine *trifluoperazine† (FGA)*	Behavioral Disorders: no age specified Psychosis: 6 and older	1–2 mg daily depending on the size of the child 1–15 mg daily (some older children with severe symptoms may require, and be able to tolerate, higher dosages)	*Warnings and precautions:* May cause CNS collapse, CNS depression, blood dyscrasias, bone marrow depression, and hepatic impairment. *Pregnancy:* studies in pregnant women showed no casual relationship between the drug and congenital malformations. *Lactation:* There is evidence that trifluoperazine is excreted in the milk of nursing mothers.
Geodon *ziprasidone* (SGA)*	18 and older	N/A	*Warnings and precautions:* 1) Doses should be administered with food. 2) Use can cause prolonged QTc interval. *Pregnancy:* No adequate and well-controlled studies in pregnant women. In animal studies, ziprasidone demonstrated developmental toxicity, including fetal structural abnormalities and possible teratogenic effects at doses similar to human therapeutic doses. *Lactation:* It is not known whether ziprasidone or its metabolites are excreted in human breast milk. It is recommended that women receiving ziprasidone should not breastfeed.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
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 major depressive disorder and other psychiatric disorders. Monitor for worsening and emergence of suicidal thoughts and behaviors. ‡ Tricyclic antidepressants (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 Selective Serotonin-Reuptake Inhibitors (SSRI) and all Serotonin and Norepinephrine Re-uptake Inhibitors (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 that have failed other agents because of the strict dietary restrictions and side effects. Patients must avoid foods that are high in tyramine and avoid 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. *Pregnancy effects for SSRIs/SNRIs:* Babies exposed to SSRIs and SNRIs late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Other clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying.			
Elavil *amitriptyline‡ (tricyclic [TCA])*	18 and older	N/A	*Warnings and precautions:* According to the label, the safety and efficacy of amitriptyline in pediatric patients has not been established. It is recommended that this drug not be used in patients under 12 years of age due to lack of experience with the use of this drug in pediatric patients. *Pregnancy:* 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. *Lactation:* 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.
Asendin *amoxapine‡ (TCA)*	18 and older	N/A	*Warnings and precautions:* Most common adverse events are drowsiness, dry mouth, constipation, and blurred vision. *Pregnancy:* No teratogenic effects were observed in mice, rat, and rabbit studies. Amoxapine should only be used during pregnancy if benefit outweighs risk to fetus. *Lactation:* Amoxapine is excreted in human breast milk. Caution should be exercised when used in nursing women.

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Antidepressant Medications *continued*			
Wellbutrin, WellbutrinSR, Wellbutrin XL, Zyban *bupropion (aminoketone class)*	18 and older	N/A	*Warnings and precautions:* 1) Contraindicated in those with seizure disorders or a current or prior diagnosis of bulimia or anorexia. 2) Can increase blood pressure. 3) Can cause false positive urine test results for amphetamines. *Pregnancy:* Data from international bupropion Pregnancy registry (675 first trimester patients) and a retrospective cohort study using the United Healthcare database (1213 first trimester exposures) did not show an increased risk for malformations. Animal data did not show increased risk of teratogenicity. *Lactation:* Bupropion and its metabolites are excreted in human breast milk.
Celexa *citalopram* (SSRI)*	18 and older	N/A	*Pregnancy:* No adequate and well controlled studies in pregnant women . Animal reproduction studies have shown negative consequences on fetal and postnatal development including teratogenic effects when administered at doses greater than human therapeutic doses. *Lactation:* 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 when given to a nursing woman.
Anafranil *clomipramine‡ (TCA)*	OCD: 10 and older	25–200 mg daily or 3 mg/kg/day, whichever is less	*Warnings and precautions:* 1) The most commonly observed adverse events are gastrointestinal complaints (including dry mouth, constipation, nausea, dyspepsia, anorexia, tremor, dizziness, and nervousness. 2) Seizure was 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. *Pregnancy:* 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. *Lactation:* Clomipramine is excreted in human breast milk.
Pristiq *desvenlafaxine ∞ ¥ (SNRI)*	18 and older	N/A	*Pregnancy:* No adequate and well-controlled studies in pregnant women. Based on animal data, desvenlafaxine may cause fetal harm. *Lactation:* Desvenlafaxine is excreted in human breast milk.

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Antidepressant Medications *continued*			
Sinequan *doxepin‡ (TCA)*	18 and older	N/A	*Warnings and precautions:* 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. *Pregnancy:* Safety in pregnancy has not been established. *Lactation:* There have been reports of apnea and drowsiness occurring in nursing mothers taking doxepin.
Cymbalta *duloxetine∞¥ (SNRI)*	Generalized Anxiety Disorder (GAD): 7 and older	30–120 mg daily	*Pregnancy:* No adequate and well controlled studies in pregnant women; Use in pregnancy only if the potential benefit justifies the potential risk to the fetus. *Lactation:* Duloxetine is excreted in human breast milk.
Lexapro *escitalopram* (SSRI)*	Major Depressive Disorder (MDD): 12 and older	10–20 mg daily	*Pregnancy:* No adequate and well controlled studies in pregnant women; Use in pregnancy only if the potential benefit justifies the potential risk to the fetus. *Lactation:* 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 when escitalopram is given to a nursing woman.
Prozac *fluoxetine* (SSRI)*	MDD: 8 and older Obsessive compulsive disorder (OCD): 7 and older	10–20 mg daily (MDD) 10–60 mg daily (OCD)	*Pregnancy:* 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. Prozac should be used in pregnancy only if the potential benefit justifies the potential risks to the fetus. *Lactation:* Fluoxetine is excreted in human breast milk. Nursing while taking fluoxetine is not recommended.
Luvox *fluvoxamine* (SSRI)*	OCD: 8 and older	25–200 mg daily (kids over age 11 may need doses up to 300 mg daily)	*Warnings and precautions:* 1) Luvox CR is not indicated in children/adolescents. 2) May cause decreased appetite and weight loss have been observed with pediatric use. Regular monitoring of weight and growth is recommended. *Pregnancy:* The effect on labor and delivery in humans is unknown. *Lactation:* Fluvoxamine is excreted in human breast milk so the decision of whether to discontinue nursing or discontinue the drug should take into account the potential for serious adverse effects from exposure to fluvoxamine in the nursing infants as well as the potential benefit of therapy to the mother.

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Antidepressant Medications *continued*			
Tofranil *imipramine‡ (TCA)*	Bedwetting: 6 and older	Ages 6–11: 25-50 mg daily Ages 12 and older: 25–75 mg daily *Do not exceed 2.5 mg/kg/day* *Give one hour before bedtime*	*Warnings and precautions:* 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 *continued* 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. *Pregnancy:* 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. *Lactation:* Likely to be excreted in human breast milk.
Marplan *isocarboxazid (MAOI)*	18 and older	N/A	*Warnings and precautions:* 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. *Pregnancy:* Safety in pregnancy has not been established. *Lactation:* Levels of excretion into breast milk and effects on nursing infants is unknown.
Fetzima *levomilnacipran (SNRI)*	18 and older	N/A	*Pregnancy:* Safety in pregnancy has not been established. *Lactation:* It is not known if levominalcipran is excreted in human breast milk. Studies have shown that it is present in the milk of lactating rats.
Ludiomil *maprotiline‡ (TCA)*	18 and older	N/A	*Pregnancy:* Safety in pregnancy has not been established. *Lactation:* Maprotiline is excreted in human breast milk. Caution should be exercised when given to a nursing mother.
Remeron *mirtazapine (tetracyclic)*	18 and older	N/A	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. There were no teratogenic effects seen in animal studies. *Lactation:* Mirtazapine may be excreted into human breast milk so caution should be exercised when administered to nursing women.

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Antidepressant Medications *continued*			
Pamelor *nortriptyline‡ (TCA)*	18 and older	N/A	*Warnings and precautions:* 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"). *Pregnancy:* Safe use during pregnancy has not been established. Animal studies have yielded inconclusive results. *Lactation:* Safe use during lactation has not been established. Animal studies have yielded inconclusive results.
Paxil, Paxil CR *paroxetine* (SSRI)*	18 and older	N/A	*Warnings and precautions:* 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. *Pregnancy:* Pregnancy Category D as a result of scientific evidence of positive teratogenic effects, particularly cardiovascular malformations. Paroxetine should be avoided in pregnancy if possible. *Lactation:* Paroxetine is excreted in human breast milk.
Nardil *phenelzine (MAOI)*	18 and older	N/A	*Pregnancy:* Safety in pregnancy has not been established. *Lactation:* Safety in lactation has not been established.
Vivactil *protriptyline‡ (TCA)*	18 and older	N/A	*Warnings and precautions:* 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 "adolescent" and maximum doses were not given). *Pregnancy:* Safety in pregnancy has not been established. *Lactation:* Safety in lactation has not been established.
Emsam (patch) *selegiline (MAO-B inhibitor/ phenethylamine class)*	18 and older	N/A	*Pregnancy:* No adequate and well-controlled studies in pregnant women. *Lactation:* 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.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
Antidepressant Medications *continued*			
Zoloft *sertraline* (SSRI)*	OCD: 6 and older	25–200 mg daily	*Warnings and precautions:* 1) Solution contains 12% alcohol. 2) Studies in depression were not sufficient to support an indication for pediatric use. *Pregnancy:* Overall, available published studies suggest no difference in major birth defect risk. No teratogenicity was observed in animal studies. *Lactation:* Sertraline is excreted in human breast milk. In a published pooled analysis of 53 mother infant pairs, exclusively human milk fed, showed no adverse reactions in the breastfed infants.
Parnate *tranylcypromine (MAOI)*	18 and older	N/A	*Pregnancy:* No adequate or well controlled studies in pregnant women. Animal reproductive studies show that tranylcypromine passes through the placental barrier to the fetus of rats. *Lactation:* Tranylcypromine is excreted in human breast milk.
Desyrel, Oleptro *trazodone (serotonin antagonist and reuptake inhibitor [SARI] class)*	18 and older	N/A	*Warnings and precautions:* 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. *Pregnancy:* 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. *Lactation:* Trazodone and its metabolites are found in the milk of lactating rats.
Surmontil *trimipramine‡ (TCA)*	18 and older	N/A	*Warnings and precautions:* 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 "adolescent"). *Pregnancy:* 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. *Lactation:* Effects in the nursing infant are unknown.
Effexor, Effexor XR *venlafaxine∞ (SNRI)*	18 and older	N/A	*Warnings and precautions:* 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 were not sufficient to support a claim for use in pediatric patients. *Pregnancy:* 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. *Lactation:* Venlafaxine is excreted in human breast milk.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
Antidepressant Medications *continued*			
Viibryd *vilazodone (atypical antidepressant)*	18 and older	N/A	*Pregnancy:* No adequate or well controlled studies in pregnant women. There were no teratogenic effects seen when given to pregnant rats or rabbits. *Lactation:* 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.
Trintellix *Vortioxetine (atypical antidepressant – serotonin modulator)*	18 and older	N/A	*Warnings and precautions:* Product underwent a name change from Brintellix to Trintellix on 5/2/16 to decrease the risk of prescribing and dispensing errors due to name confusion with Brilanta, an antiplatelet medication. *Pregnancy:* 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. There were no teratogenic effects seen in rats or rabbits. *Lactation:* It is not known whether vortioxetine is excreted in human breast milk. It is present in the milk of lactating rats.
Mood Stabilizing and Anticonvulsant Medications			
Tegretol, Tegretol XR, Carbatrol, Epitol *carbamazepine*	Seizures: any age	Under 6: 10–35 mg/kg/day Sge 6–12: 20–1000 mg daily Age 13–15: 400–1000 mg daily Age 16 and older: 400–1200 mg daily **Recommended therapeutic serum levels: 4-12 mcg/mL**	*Black Box Warning:* 1) Stevens-Johnson Syndrome (particularly among Asians) 2) Aplastic anemia 3) Agranulocytosis. *Warnings and precautions:* 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 6. *Pregnancy:* May cause fetal harm when administered to pregnant women. Data suggest that there may be an association with congenital malformations (including spina bifida), congenital anomalies, and development disorders. *Lactation:* Carbamazepine and its metabolite are excreted into human breast milk.
Equetro *carbamazepine extended release capsules*	18 and older	N/A	*Black Box Warning:* 1) Stevens-Johnson Syndrome (particularly among Asians) 2) Aplastic anemia 3) Agranulocytosis *Pregnancy:* May cause fetal harm when administered to pregnant women. Data suggest that there may be an association with congenital malformations (including spina bifida), congenital anomalies, and development disorders. *Lactation:* Carbamazepine and its metabolite are excreted into human breast milk.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
Mood Stabilizing and Anticonvulsant Medications *continued*			
Depakote, Depakote ER, Depakote Sprinkles *divalproex sodium* — Depakene, Stavzar *valproic acid*	Seizures (monotherapy and adjunctive): 10 and older	10–60 mg/kg/day Recommended therapeutic serum levels: 50–100 mcg/mL	*Black Box Warning:* 1) Hepatoxicity 2) Teratogenicity 3) Pancreatitis *Warnings and precautions:* 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. *Pregnancy:* Can cause congenital malformations including neural tube defects and decreased IQ. *Lactation:* Excreted in human breast milk.
Neurontin *gabapentin*	Seizures (adjunct): 3 and older	Ages 3–11: 10–50 mg/kg/day Ages 12 and older: 900–2400 mg daily (Doses of 3600 mg/day have also been administered to a small number of patients for short duration and have been well tolerated)	*Warnings and precautions:* Dosage adjustments necessary for renal impairment or those undergoing hemodialysis. *Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Gabapentin is excreted in human breast milk.
Lamictal, Lamictal XR *lamotrigine*	Epilepsy (adjunct): 2 and older Epilepsy (monotherapy): 16 and older	*Adjunct dosing:* Age 2–12: 0.15–15 mg/kg/day or maximum 300 mg daily (max dose is 400 mg daily if taking conflicting medications) 12 and older: 25 mg every other day – 375 mg daily (max dose is 500 mg daily if taking conflicted medications) **above doses may have to be increased or decreased for those patients taking concomitant valporate, carbamazepine, phenytoin, phenobarbital, or primidone** *Monotherapy dosing:* 16 and older: 200–500 mg daily	*Black Box Warning:* Life threatening serious rashes including Stevens-Johnson Syndrome. The rate of serious rash is greater in pediatric patients than in adults. *Warnings and precautions:* 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 bipolar disorder or 1 to 2 year olds for adjunct therapy for seizures was not established. *Pregnancy:* No adequate and well controlled studies in pregnant women. In animal studies, lamotrigine was developmentally toxic at doses lower than those administered clinically. *Lactation:* Lamotrigine is excreted in human breast milk. Apnea, drowsiness, and poor sucking have been reported in milk fed infants exposed to lamotrigine.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
Mood Stabilizing and Anticonvulsant Medications *continued*			
Eskalith, Lithobid *lithium carbonate/ citrate*	Bipolar Mania: 12 and older	300–2,400 mg daily Therapeutic serum levels: 0.6–1.2 mEq/L (toxic concentrations seen at levels greater than 1.5 mEq/L)	*Black Box Warning:* Toxicity above therapeutic serum levels. *Warnings and precautions:* 1) May cause renal function impairment, polyuria, tremor, diarrhea, nausea, and hypothyroid. 2) Patients with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion are at higher risk of toxicity. *Pregnancy:* Lithium may cause fetal harm when administered to a pregnant woman. Data from lithium birth registries suggest an increase in cardiac and other abnomalies. If possible, lithium should be withdrawn for at least the first trimester. *Lactation:* Lithium is excreted in human breast milk. It is recommended to try to avoid breastfeeding while on lithium.
Trileptal *oxcarbazepine*	Seizures (monotherapy): 4 and older Seizures (adjunct): 2 and older	Monotherapy: 600–2100 mg daily (initiate at 8–10 mg/kg/day) Adjunct: 150–1,800 mg daily (8–60 mg/kg/day) **Max doses are dependent on patient's weight**	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled clinical studies in pregnant women. Closely related structurally to carbamazepine which is considered to be teratogenic in humans. Animal studies show the potential for harm to the fetus as well. *Lactation:* Oxcarbazepine and its active metabolite are excreted in human breast milk.
Topamax, Topamax XR *topiramate*	Epilepsy (monotherapy and adjunctive): 2 and older Migraine: 12 and older	*Monotherapy:* 10 and older: 25–400 mg daily (for those < 10, there are specific weight based maxes) *Adjunctive:* Age 2–16: 25 mg daily–9 mg/kg/day (Recommended dose: 5–9 mg/kg/day) 17 and older: 25–400 mg daily 25–100 mg daily (migraines)	*Warnings and precautions:* 1) Because of the bitter taste, tablets should not be broken. 2) Decreases the efficacy of contraceptives and can cause increased breakthrough bleeding. *Pregnancy:* 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. *Lactation:* Topiramate is excreted in human breast milk. The effects of topiramate exposure on breastfed infants are unknown.
Trokendi XR, Qudexy XR *topiramate*	Epilepsy (monotherapy and adjunctive therapy): 6 and older	*Monotherapy:* Ages 6–9: 25 mg–400 mg daily Age 10 and older: 50–400 mg daily *Adjunctive:* 25 mg daily–9 mg/kg/day (Recommended dose: 5–9 mg/kg/day) **Max doses are dependent on the child's weight**	*Warnings and precautions:* 1) Decreases the efficacy of contraceptives and can cause increased breakthrough bleeding. 2) Capsules have to be swallowed whole and may not be sprinkled on food, crushed or chewed. *Pregnancy:* 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. *Lactation:* Topiramate is excreted in human breast milk. The effects of topiramate exposure on breastfed infants are unknown.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
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 central nervous system. *Warnings in pregnancy/lactation for benzodiazepines:* 1) Have been associated with negative outcomes in pregnant women including *teratogenicity*. Use of benzodiazepines during pregnancy, particularly in the first trimester, generally increases the risk of congenital malformations and decreases viability. 2) Because of the potential for adverse effects in nursing infants, such as sedation, feeding difficulties, breathing difficulties, feeding difficulties, and weight loss, it is generally not recommended to breast feed during use.			
Xanax *alprazolam*	18 and older	N/A	
Buspar *buspirone*	Generalize Anxiety Disorder: 6–17 years	7.5 mg–60 mg daily	*Lactation:* 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 *chlordiazepoxide*	Anxiety: 6 and older	10–30 mg daily	
Klonopin *clonazepam*	18 and older	N/A	
Tranxene *clorazepate*	Partial Seizures: 9–12 years	15–60 mg daily	*Warnings and precautions:* Recommended to monitor blood count and liver function tests.
Valium *diazepam*	Anxiety: 6 months and older	1 mg to 2.5 mg, 3 or 4 times daily initially; increase gradually as needed and tolerated	*Warnings and precautions:* 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.
Ativan *lorazepam*	Anxiety: 12 and older	2–10 mg daily	
Serax *oxazepam*	18 and older	N/A	
ADHD Medications (Drugs below are stimulants, except atomoxetine, clonidine and guanfacine)			
Classification of non-stimulant drugs: (1) atomoxetine is a selective norepinephrine reuptake inhibitor or NRI; (2) clonidine and (3) guanfacine are classified as alpha-2 receptor agonists. *Black Box Warning for all stimulants:* Abuse potential. Risk of sudden death and serious cardiovascular events. *Warnings/precautions for all stimulants:* 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. *Warnings for all amphetamines:* Infants born to mothers 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.			
Evekeo *amphetamine sulfate*	ADHD: 3 and older Narcolepsy: 6 and older Exogenous obesity: 12 and older	2.5–40 mg daily (ADHD) 5–60 mg daily (Narcolepsy) Up to 30 mg daily (take in divided doses) 30–60 minutes before meals (exogenous obesity)	*Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
ADHD Medications *continued*			
Adzenys XR *amphetamine extended release*	ADHD: 6 and older	Ages 6–12: 6.3–18.8 mg daily Ages 13 and older: 6.3–12.5 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Dyanavel XR *amphetamine extended release*	ADHD: 6 and older	2.5–20 mg daily	*Warnings and precautions:* 1) Liquid solution that needs to be shaken prior to use. 2) Do not substitute for other amphetamine products on a mg/mg basis *Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Adderall *Mixed amphetamine salts*	ADHD: 3 and older Narcolepsy: 6 and older	2.5–40 mg daily (ADHD) 5-60 mg daily (Narcolepsy)	*Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Adderall XR *Mixed amphetamine salts extended release*	ADHD: 6 and older	Ages 6–12: 10-30 mg daily Ages 13 and older: 10-20 mg daily	*Warnings and precautions:* Capsule may be opened and sprinkled on soft foods. *Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Strattera *atomoxetine*	ADHD: 6 and older	Up to 70 kg: 0.5–1.4 mg/kg (lesser of 1.4 mg/kg or 100 mg) Over 70 kg: 40–100 mg daily	*Black Box Warning:* Increased risk of suicidal ideation in children or adolescents. *Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* 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.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
ADHD Medications *continued*			
Kapvay *clonidine extended release (ER)*	ADHD (monotherapy or adjunct to stimulants): 6–17	0.1–0.4 mg daily	*Warnings and precautions:* 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. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* Clonidine is excreted in human breast milk.
Focalin *dexmethylphenidate*	ADHD: 6–17	5–20 mg daily	*Pregnancy:* Limited human data. Based on animal data, may cause fetal harm. *Lactation:* It is not known whether dexmethylphenidate is excreted in human breast milk.
Focalin XR *dexmethylphenidate extended release*	ADHD: 6 and older	5–30 mg daily	*Warnings and precautions:* 1) Capsule contents can be sprinkled on applesauce and swallowed whole. 2) Capsule should not be crushed, chewed, or divided. *Pregnancy:* Limited human data. Based on animal data, may cause fetal harm. *Lactation:* It is not known whether dexmethylphenidate is excreted in human breast milk.
Dexedrine, ProCentra Oral Solution, Zenzedi, DextroStat *dextroamphetamine*	ADHD: 3 and older Narcolepsy: 6 and older	2.5–40 mg daily (ADHD) 5–60 mg daily (narcolepsy)	*Warnings and precautions:* Extended release spanules can be used once a day when appropriate, tablets need to be given multiple times per day at intervals of 4–6 hours. *Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Intuniv *guanfacine extended release*	ADHD (monotherapy and adjunct to stimulants): 6 and older	Ages 6–12: 1–4 mg daily (lesser of 0.12 mg/kg or 4 mg daily) Ages 13–17: 1–7 mg daily **max dose depends on weight of child**	*Warnings and precautions:* 1) Sedation, somnolence, and fatigue are common and tend to decline over time. 2) Do not crush, chew or break tablets. 3) Do not administer with high fat meal. 4) Do not discontinue abruptly. 5) Dosage adjustments necessary if used with Strong 3A4 inhibitors or inducers. 6) Immediate release guanfacine/Tenex is only approved for hypertension in patients 12 and older. *Pregnancy:* No adequate or well controlled studies in pregnant women. *Lactation:* It is not known whether guanfacine is excreted in human breast milk; however it is excreted in rat milk.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
ADHD Medications *continued*			
Vyvanse *lisdexamfetamine dimesylate*	ADHD: 6–17	30–70 mg daily	Additional Information: 1) Dosage adjustments needed for renal impairment. 2) Capsules can be opened and mixed in yogurt, water, or orange juice. The contents should be mixed until completely dispersed and the entire mixture should be consumed immediately. *Pregnancy:* Limited available data from published literature and postmarketing reports are not sufficient to inform a drug associated risk for birth defects and miscarriage. *Lactation:* Amphetamines are present in human breast milk.
Desoxyn *methamphetamine*	ADHD: 6 and older Obesity (short term): 12 and older	5–25 mg daily 5 mg thirty minutes before each meal; treatment should not exceed a few weeks.	*Pregnancy:* No adequate or well controlled studies in pregnant women. Based on animal data, may cause fetal harm. *Lactation:* Amphetamines are excreted in human breast milk.
Ritalin, Methylin *methylphenidate*	ADHD: 6 and older	10–60 mg daily	*Warnings and precautions:* Methylin is a chewable tablet. It should be taken with at least 8 ounces of water or other fluid to prevent choking. *Pregnancy:* There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however the data are insufficient to inform any drug associated risks. *Lactation:* Limited published literature reports that methylphenidate is present in human breast milk.
Methylin ER, Metadate ER, Ritalin SR, Aptensio XR *methylphenidate extended release*	ADHD: 6 and older	10–60 mg daily	*Warnings and precautions:* 1) Aptensio XR capsules can be opened and the contents can be sprinkled over a spoonful of applesauce. This mixture should be consumed in its entirety. 2) Ritalin SR tablets must be swallowed whole and never crushed or chewed. *Pregnancy:* There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however the data are insufficient to inform any drug associated risks. *Lactation:* Limited published literature reports that methylphenidate is present in human breast milk.

Drug Brand Name / Generic Name	FDA Approved *Age/Indication*	Pediatric Dosage/ Serum Level when applicable	Black Box Warnings/Warnings and Precautions/ Additional Information
ADHD Medications *continued*			
Ritalin LA, Metadate CD, QuilliChewER, Quillivant XR *methylphenidate extended release*	ADHD: 6 and older	20–60 mg daily	*Warnings and precautions:* 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. *Pregnancy:* There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however the data are insufficient to inform any drug associated risks. *Lactation:* Limited published literature reports that methylphenidate is present in human breast milk.
Concerta *methylphenidate long acting*	ADHD: 6 and older	Ages 6–12: 18–54 mg daily Ages 13–17: 18–72 mg daily (not to exceed 2mg/kg/day)	*Warnings and precautions:* Should be swallowed whole and not chewed or crushed. *Pregnancy:* There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however the data are insufficient to inform any drug associated risks. *Lactation:* Limited published literature reports that methylphenidate is present in human breast milk.
Daytrana *methylphenidate patch*	ADHD: 6-17	10-30 mg daily	*Warnings and precautions:* Should be applied to the hip area two hours before an effect is needed and removed nine hours after application (alternate hips). *Pregnancy:* There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however the data are insufficient to inform any drug associated risks. *Lactation:* Limited published literature reports that methylphenidate is present in human breast milk.

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Psychotropic Drugs—Side Effects and Teratogenic Risks (interference with embryo/fetal growth)

Class of Drugs	Typical Side Effects	Possible Teratogenic Risk	Risk Category*
Antipsychotic Medications	• Akathisia and dystonic reactions are seen in children treated with SGAs but risk of tardive dyskinesia is small compared to FGAs. • Weight gain is a significant problem with SGAs. Other side effects: constipation, dry mouth, dizziness. • Sedation/cognitive blunting may occur with FGAs and SGAs. • Adolescent males at much greater risk for dystonic reactions than adults. • Significant drop in neutrophils and increased risk of seizures with clozapine (should be used as treatment of last resort).	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 be responsible for 4 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-amitriptyline, Imipramine, nortriptyline C- (other TCAs)/ 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
	• 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, Treatment- emergent akathisia from SSRIs may be more evident in pediatric depression associated with bipolar disorder and greater suicide risk.	SSRIs: Perinatal and cardiovascular complications, spontaneous abortions. Potential premature delivery and neonatal persistent pulmonary hypertension (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

**Note: Risk Categories: 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	Risk Category*
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 anomaly) and behavioral effects.	D
	• Valproate: Children younger than 2 yrs. are at greatest risk for hepatotoxicity. Common reactions: headache, nausea/vomiting, loss of muscle strength, somnolence, thrombocytopenia, dyspepsia, dizziness, diarrhea, abdominal pain, 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, 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, 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, decreased platelets.		C
Anti-anxiety Medications	• 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. • Sedative antihistamines may have some antianxiety or hypnotic ability. Prolonged used of these agents may lead to anticholinergic side effects and cognitive impairment. • Buspirone can cause drowsiness, dizziness, impaired concentration, nausea and headache. Depression, hostility and akathisia, dystonia, tardive dyskinesia and EPS can occur.	BZDs: "Floppy baby", withdrawal, increased risk of cleft lip or palate. Hypnotic BZDs: Decreased intrauterine growth Buspirone: Unknown	D/X (hypnotic BZDs) C

Sources: (1) Schatzberg AF, Cole JO, DeBattista C. (2010) Manual of Clinical Psychopharmacology. (7th ed.). Arlington VA: American Psychiatric Publishing, Inc. (2) Hilt RJ. Monitoring Psychiatric Medications in Children. Pediatric Annals. April 2012, Volume 41, Issue 4: 157-163. (3) Solchany J. Psychotropic Medication and Children in Foster Care: Tips for Advocates and Judges. Practice and Policy Brief, American Bar Association Center on Children and the Law. October 2011. (4) FDA Alerts [7/2006]: Increased Risk of Neonatal Persistent Pulmonary Hypertension. Information for Healthcare Professionals: Paroxetine (Marketed as Paxil). Accessed website on February 20, 2013 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm084319.htm (5) Yonkers KA, Wisner KL, Stewart DE, Oberlander TF, Dell DL, Stotland N, Ramine S, Chaudron L, Lockwood C. The Management of Depression During Pregnancy: A Report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. Focus, Winter 2012, Vol. X, No. 1.

Recommended Clinical Monitoring of Children and Adolescents for Select Psychotropic Drugs

Class of Drugs	Monitoring Recommendation	Frequency Suggestion
Atypical Antipsychotic Medications	1. Height and weight 2. Labs: fasting blood sugar, fasting triglyceride/cholesterol 3. Screen for dyskinesia movements 4. Labs: CBC with differential values (diff) 5. Blood Pressure/pulse 6. Cardiac history 7. Determine if treatment responsive.	1. At baseline and at each follow-up visit (at least every 6 months) 2. At least every 6 months 3. At least every 6 months 4. Once, 2 – 3 months after start of drug 5. At least once after start of drug 6. At baseline and obtain ECG if in doubt about risk from a mild QT increase 7. Repeat disorder-specific rating scales(s) until remission is achieved. Increase at 4 – 6 week intervals if insufficient drug benefit
Antidepressant (SSRI) Medications	1. Blood pressure monitoring 2. Hepatic Function testing 3. Assess for suicidal thinking/behaviors, clinical worsening or other changes in behaviors 4. Inquire about activation symptoms 5. Inquire about bleeding/bruising 6. Measure height and weight 7. Determine treatment response 8. Pregnancy testing	1. Prior to treatment and with dose titration 2. Baseline and as clinically indicated 3. Ongoing—usually around week 2, weeks 4 – 6 and other visits 4. Screen for new irritability or agitation around week 2 and weeks 4–6 5. At least once after treatment begins 6. At baseline and each F/U visit, at least every 6 months 7. Repeat disorder-specific rating scales(s) until remission is achieved. Increase at 4–6 week intervals if insufficient drug benefit 8. As clinically indicated
Antidepressant (SNRI) Medications	1. Blood pressure 2. Hepatic function 3. Monitor for emergence of suicidal ideation or behavior 4. Pregnancy testing	1. Prior to initiating treatment, during dosage titration and as clinically indicated 2. At baseline and as clinically indicated 3. Ongoing—usually around week 2, weeks 4–6 and other visits 4. As clinically indicated
Tricyclic Antidepressant Medications	1. Electrocardiograms (ECGs) 2. Obtain outside consultation 3. Lower dosage with significant slowing of cardiac conduction 4. Monitor for emergence of suicidal ideation or behavior	1. Prior to staring TCA therapy, when dose exceeds 3mg/kg and then every 2 weeks if dose is being increased 2. When prescribing doses > 5 mg/kg 3. In cases with ECG findings: PR interval over 0.20 msec, QRS interval over 0.12 msec 4. Ongoing—usually around week 2, weeks 4–6 and other visits

Class of Drugs	Monitoring Recommendation	Frequency Suggestion
Stimulant Medications	1. Height and weight 2. Blood pressure and pulse 3. Cardiac history 4. Refill monitoring 5. CBC with diff 6. Determine if treatment response.	1. At baseline and each F/U visit, at least every 6 months 2. At baseline and at least once on a given dose of medication 3. At baseline to determine if any risks from adrenergic stimulation 4. Track date of each refill to identify signs of drug diversion 5. For methylphenidate only, at least once every 6 months 6. Repeat ADHD-specific rating scale(s) until remission is achieved. Increase at 2 to 4 weeks if insufficient response
Mood Stabilizing and Anticonvulsant Medications	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. 2. Divalproex sodium: (a) Chemistry Panel, CBC with platelets, liver function tests, pregnancy test. (b) Serum drug levels, hepatic and hematological indices. 3. Carbamazepine: (a) CBC, electrolytes and liver function tests. (b) Therapeutic drug levels.	1. Baseline monitoring (b) every 3–6 months 2. Baseline monitoring (b) every 3–6 months 3. Baseline monitoring (b) Routine monitoring in growing children to check for autoinduction of carbamazepine—usually occurring after one week and/or dosage changes

Sources: (1) Hilt RJ. Monitoring Psychiatric Medications in Children. Pediatric Annals. April 2012, Volume 41, Issue 4: 157-163. (2) Texas Department of Family and Protective Services and the University of Texas at Austin College of Pharmacy. Psychotropic Medication Utilization Parameters for Foster Children. December 2010. (3) Schatzberg AF, Cole JO, DeBattista C. (2010) Manual of Clinical Psychopharmacology. (7th ed). Arlington VA: American Psychiatric Publishing, Inc. (4) McClellan J, Kowatch, Findling RL, and the Work Group on Quality Issues. Practice Parameter for the Assessment and Treatment of Children and Adolescents with Bipolar Disorder. J Am Acad Child Adolesc Psychiatry 46:1, January 2007. (5) Epocrates Online [https://online.epocrates.com/u/1000/Drugs?ICID=search-drugs] (6) Autoinduction and steady-state pharmacokinetics of carbamazepine and its major metabolites. Br J Clin Pharmac (1992), 33, 611-615.