

# Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by The Law Project for Psychiatric Rights (PsychRights)

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
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<b>Key:</b>	<b>White Background: Medically Accepted Indication</b>
	<b>Orange Background: Pediatric Indication cited, but not supported by DRUGDEX</b>
	<b>Red Background: No Pediatric FDA Approval or DRUGDEX citation</b>

<b>Abilify</b> (Aripiprazole) - Antipsychotic				
	Autistic disorder-Psychomotor agitation	Yes (6-17)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		

<b>Adderall</b> (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug)		
	Narcolepsy	Yes (for 6 years old and up (immediate release only))		

<b>Ambien</b> (zolpidem) - nonbarbiturate Hypnotic				
	Insomnia, Short-term treatment	No		Class III

<b>Anafranil</b> (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
	Depression	No		Class IIb

<b>Ativan</b> (lorazepam) - Antianxiety, Anticonvulsant, Benzodiazepine, Short or Intermediate Acting, Skeletal Muscle Relaxant.				
	Anxiety	Yes, oral only, 12 years and older		
	Chemotherapy-induced nausea and vomiting; Prophylaxis	No	Class IIa	
	Insomnia, due to anxiety or situational stress	Yes		
	Seizure	No	Class IIa	
	Status epilepticus	No	Class IIa	
	Premedication for anesthetic procedure	No		Class IIb
	Sedation	No		Class IIb
	Seizure, drug-induced; Prophylaxis	No		Class IIb

<b>Buspar</b> (buspirone) - Antianxiety, Azaspirodeconedione				
	Anxiety	No		Class III
	Autistic disorder	No		Class IIb
	Behavioral syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb

<b>Celexa</b> (citalopram) - Antidepressant, Serotonin Reuptake Inhibitor				
	Depression	No		None
	Obsessive-compulsive disorder	No		Class IIb
	Panic disorder	No		Class IIb
	posttraumatic stress disorder	No		Class IIb

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<b>Clozaril</b> (clozapine) – Antipsychotic; Dibenzodiazepine				
	Bipolar I Disorder	No		Class IIb
	Schizophrenia, Treatment Resistant	No		cited, with no recommendation level
<b>Concerta</b> (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years old)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up) re ConcertaR		
	Autistic Disorder	No		Class IIb
	Impaired Cognition - inding related to coordination/ in coordination	No		Class IIb
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
<b>Cymbalta</b> (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor				
<b>Dalmane</b> (flurazepam) - Benzodiazepine, Long Acting, Hypnotic				
	Insomnia	Yes, 15 years and older		
<b>Depakote/Depakene</b> (valproate/valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class)				
	Absence Seizure, Simple and Complex	Yes (10 years and older)		
	Complex Partial Epileptic Seizure	Yes (10 years and older)		
	Seizure, Multiple seizure types; Adjunct	Yes (10 years and older)		
	Bipolar I disorder, Maintenance	No		Class IIb
	Bipolar II disorder, Maintenance	No		Class IIb
	Chorea	No		Class IIb
	Febrile Seizure	No		Class IIb
	Mania	No		Class III
	Manic bipolar I disorder	No		Class IIb
	Mental Disorder - Mood Disorder	No		Class IIb
	Migraine; Prophylaxis	No		Class IIb
	Status epilepticus	No		Class IIb
	West syndrome	No		Class IIb
<b>Desyrel</b> (trazodone) - Antidepressant; Triazolopyridine				
	Migraine, Pediatric; Prophylaxis	No		Class III
<b>Dexedrine</b> (dextroamphetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))		
	Narcolepsy	Yes (for 6 years old and up)		
<b>Effexor</b> (venlafaxine) – Antidepressant; Antidepressant, Bicyclic; Phenethylamine (class); Serotonin/ Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	No		Class IIb
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Social Phobia	No		Class IIb
<b>Focalin</b> (dexmethylphenidate) - Amphetamine Related; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
<b>Geodon</b> (ziprasidone) - Antipsychotic; Benzisothiazoyl				

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<b>Haldol</b> (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis	Gilles de la Tourette's syndrome	Yes (for 3 years old and up)	It does not appear the injectible form (decanoate) is FDA approved for any pediatric use, nor is it supported by DRUGDEX for any indication.		
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	Yes (for 3 years old and up)			
	Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy	Yes (for 3 years old and up)			
	Psychotic Disorder	Yes (for 3 years old and up but ORAL formulations only)			
	Schizophrenia	Yes (for 3 years old and up but ORAL formulations only)			
	Agitation	No			Class IIb
	Migraine	No			Class III
<b>Invega</b> (paliperidone) - Antipsychotic; Benzisoxazole					
<b>Klonopin</b> (clonazepam) - anti-anxiety, Anticonvulsant, Benzodiazepine, Short or Intermediate Acting					
	Seizure	Yes, up to 10 years or up to 30 kg			
	Gilles de la Tourette's syndrome	No		Class IIb	
	Hyperreflexia	No		Class IIb	
	Nocturnal epilepsy	No		Class IIb	
	Panic disorder	No		Class IIb	
	Status epilepticus	No		Class IIb	
<b>Lamictal</b> (lamotrigine) - Anticonvulsant; Phenyltriazine					
	Convulsions in the newborn, Intractable	No		Class IIa	
	Epilepsy, Refractory	No		Class IIa	
	Lennox-Gastaut syndrome; Adjunct	yes (2 years and older)			
	Partial seizure, Adjunct or monotherapy	yes (13 years and older, extended-release only; 2 years and older, chewable dispersible)			
	Tonic-clonic seizure, Primary generalized; Adjunct	yes (2 years and older)			
	Absence seizure; Adjunct	No		Class IIb	
	Bipolar Disorder, Depressed Phase	No		Class IIb	
	Infantile neuronal ceroid lipofuscinosis	No		Class IIb	
	Juvenile myoclonic epilepsy	No		Class III	
	Paroxysmal choreoathetosis, Paroxysmal	No		Class IIb	
	Rett's disorder	No		Class IIb	
	Status epilepticus	No		Class IIb	
	West syndrome	No		Class IIb	
<b>Lexapro</b> (escitalopram) - Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor					
	Major Depressive Disorder	Yes (for 12 years old and up)			
<b>Limbitrol</b> (chlordiazepoxide/amitriptyline) - Tricyclic Antidepressant/Benzodiazepine Combination					
<b>Lunesta</b> (eszopiclone) - Nonbarbiturate Hypnotic					
<b>Luvox</b> (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor					
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)			
	Asperger's Disorder	No		Class IIb	

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
<b>Mellaril</b> (thioridazine) - Antipsychotic; Phenothiazine; Piperidine	Schizophrenia, Refractory	Yes		
	Behavioral Syndrome	No		Class III
<b>Moban</b> (molindone) - antipsychotic, Dihydroindolone	Schizophrenia	Yes, 12 years and older		
	Aggressive behavior, In children	No		Class IIb
<b>Neurontin</b> (gabapentin) anticonvulsant	Partial seizure; Adjunct	Yes (3- 12 years old)		
	Complex Regional Pain Syndrome, Type 1	No		Class IIb
	Neuropathic Pain	No		Class IIb
	Partial Seizure	No		Class IIb
	Partial Seizure, Refractory	No		Class III
	Phantom Limb Syndrome	No		Class IIb
<b>Orap</b> (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist	Gilles de la Tourette's syndrome	Yes (12 years and older)		
	Anorexia Nervosa	No		Class III
<b>Paxil</b> (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor	Panic disorder	No		Class IIb
	Trichotillomania	No		Class IIb
<b>Pristiq</b> (desvenlafaxine) Antidepressant, Serotonin/Norepinephrine Reuptake Inhibitor				
<b>Prozac</b> (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up)		
	Anxiety Disorder of Childhood	No		Class IIb
	Autistic disorder	No		None
	Bulimia nervosa	No		Class IIb
	Vasovagal syncope; Prophylaxis	No		Class III
<b>Restoril</b> (temazepam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting, Hypnotic				
<b>Ritalin</b> (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(extended release)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)(immediate release)		
	Narcolepsy	Yes (for 6 years and up, and Ritalin(R) -SR only)		
	Autistic disorder	No		Class IIb
	Finding related to coordination / incoordination - Impaired cognition	No		Class IIb
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
	<b>Risperdal</b> (risperidone) - Antipsychotic; Benzisoxazole			
	Autistic Disorder – Irritability	Yes (for 5 years old and up)		
	Bipolar I Disorder	Yes (for 10 years old and up)		
	Schizophrenia	Yes (for 13 years old and up, ORALLY)		
	Behavioral syndrome - Mental retardation	No		Class IIb
	Gilles de la Tourette's syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb

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<b>Rozerem</b> (ramelteon) - Melatonin Receptor Agonist, Nonbarbiturate Hypnotic				
<b>Seroquel</b> (QUETIAPINE) - Antipsychotic; Dibenzothiazepine				
	Bipolar disorder, maintenance	Yes, 10-17 regular release only (12/4/09)		
	Manic bipolar I disorder	Yes, 10-17 regular release only (12/4/09)		
	Schizophrenia	Yes 13-17, regular release only (12/4/09)		
	Gilles de la Tourette's syndrome	No		Class IIb
<b>Sinequan</b> (doxepin) - Antianxiety Antidepressant; Antidepressant, Tricyclic; Antiulcer Dermatological Agent				
	Alcoholism - Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety - Depression - Psychoneurotic personality disorder	Yes (for 12 years old and up)		
	Pruritus (Moderate), Due to atopic dermatitis or lichen simplex chronicus	No		Class IIb
<b>Sonata (zaleplon) - Nonbarbiturate Hypnotic</b>				
<b>Strattera</b> (atomoxetine) - Central Nervous System Agent; Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia	No		Class IIb
<b>Symbyax</b> (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
<b>Tegretol</b> (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Apraxia			None
	Chorea			Class IIb
	Migraine; Prophylaxis			Class IIb
	Myokymia			Class IIb
	Neuropathy, General			Class IIb
	Schwartz-Jampel syndrome			Class IIb
<b>Tofranil</b> (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class III
	Depression	No		Class IIb
	Schizophrenia, Adjunct	No		Class III
	Separation Anxiety Disorder of Childhood	No		Class III
	Trichotillomania	No		Class IIb
	Urinary incontinence	No		Class IIb
<b>Topamax</b> (topiramate) - anticonvulsant, Fructopyranose Sulfamate				
	Lennox-Gastaut syndrome; Adjunct	Yes, 2 years and older		
	Partial seizure, Initial monotherapy	Yes, 10 years and older		
	Partial seizure; Adjunct	Yes, 10 years and older		
	Tonic-clonic seizure, Primary generalized; Adjunct	Yes, 2 to 16 years old		
	Tonic-clonic seizure, Primary generalized (initial monotherapy)	Yes, 10 years and older		
	Angelman syndrome	No		Class IIb
	Migraine; Prophylaxis	No		Class IIb

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	Status epilepticus	No		Class IIb
	West syndrome	No		Class IIb
<b>Tranxene</b> (clorazepate) - Antianxiety, Anticonfulsant, Benzodiazepine, Long Acting				
	Partial seizure; Adjunct	Yes, 9 years and older		
	Epilepsy	No		Class IIb
<b>Trileptal</b> (oxcarbazepine) - Anticonvulsant; Dibenzazepine Carboxamide				
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
<b>Vyvanse</b> (lisdexamfetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
<b>Wellbutrin</b> (bupropion) - Aminoketone, Antidepressant, Smoking Cessation Agent				
	Attention deficit hyperactivity disorder	No		None
<b>Xanax</b> (alprazolam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting				
<b>Zoloft</b> (sertraline) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Obsessive-Compulsive Disorder	Yes (6 years old and up)		
	Anorexia nervosa	No		Class III
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
<b>Zyprexa</b> (olanzapine) - Antipsychotic; Thienobenzodiazepine				
	Bipolar 1, Disorder, Acute Mixed or Manic Episodes	Yes (ages 13-17), oral only, approved 12/4/09		
	Schizophrenia	Yes (ages 13-17), oral only, approved 12/4/09		
	Schizophrenia, Refractory	No		Class IIb
	Pervasive Developmental Disorder	No		Class IIb

**RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS**

**RESPONSE**

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.