



FDA approved psychotropic medications for Pediatric Use

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Question 1

Which of the following FDA-approved medications is indicated for treatment of ADHD in a 5-year-old child?

- A) Guanfacine extended-release
- B) Atomoxetine
- C) Methylphenidate immediate-release
- D) Dextroamphetamine immediate-release
- E) Clonidine Hydrochloride extended-release



Question 2

Which of the following medications is FDA-approved for treatment of Bipolar Disorder in a 10-year-old boy?

- A) Paliperidone
- B) Risperidone
- C) Olanzapine
- D) Chlorprothixene
- E) Perphenazine



Question 3

Which of the following is a FDA indication for using an atypical antipsychotic in an 8-year-old child?

- A) Schizophrenia
- B) Generalized anxiety disorder
- C) Irritability associated with Autistic disorder
- D) Tourette's syndrome
- E) Bipolar I disorder



Learning Objectives

- To be familiar with FDA-approved psychotropic medications for children and adolescents.
- Recognize and discuss the appropriate indications of each FDA-approved agent.



Outline

- **Stimulants & Non-stimulants**
- **Antipsychotics**
- **Antidepressants & Antianxiety Medications**
- **Sleep disorder agents**
- **Mood Stabilizers and Anticonvulsants**
- **Tics/Tourette syndrome agents**
- **Nocturnal enuresis agents**
- **Miscellaneous agents**



Stimulants & Non-stimulants

■ Stimulants:

- ✓ Methylphenidate formulations: ≥ 6 years for ADHD; immediate-release formulations and Ritalin(R)-SR only ≥ 6 years for Narcolepsy.
- ✓ Dextroamphetamine: immediate-release - 3-16 years for ADHD; sustained-release – 6-16 years for ADHD; ≥ 6 years for Narcolepsy.
- ✓ Lisdexamfetamine: ≥ 6 years for ADHD.
- ✓ Methamphetamine: ≥ 6 years for ADHD.
- ✓ Mixed Amphetamine Salts: immediate-release ≥ 3 years for ADHD, extended-release ≥ 6 years for ADHD, ≥ 6 years for Narcolepsy.

■ Non-stimulants:

- ✓ Atomoxetine: ≥ 6 years for ADHD.
- ✓ Clonidine Hydrochloride extended-release tablets only: ≥ 6 years for ADHD.
- ✓ Guanfacine extended-release: ≥ 6 years for ADHD.



Antipsychotics

- Typical Antipsychotics:
- ✓ Chlorpromazine: 1-12 years for severe behavioral problems.
- ✓ Chlorprothixene: oral formulation ≥ 6 years for Schizophrenia; parenteral formulation ≥ 12 years for Schizophrenia.
- ✓ Haloperidol (oral only): ≥ 3 years for hyperactive behavior, Tourette's syndrome, Schizophrenia.
- ✓ Perphenazine: ≥ 12 years for Schizophrenia.
- ✓ Pimozide: ≥ 12 years for Tourette's syndrome.
- ✓ Prochlorperazine: ≥ 2 years for Schizophrenia.
- ✓ Thioridazine: ≥ 2 years for Schizophrenia (Off market).
- ✓ Trifluoperazine: 6-12 years for Schizophrenia.
- ✓ Thiothixene: ≥ 12 years for Schizophrenia.



Antipsychotics

- Atypical Antipsychotics:
 - ✓ Aripiprazole: ≥ 6 years for Autistic disorder- psychomotor agitation; ≥ 10 years for Bipolar I disorder; ≥ 13 years for Schizophrenia.
 - ✓ Olanzapine (oral formulations only): 13-17 years for Schizophrenia and Bipolar I disorder, Acute mixed or manic episodes.
 - ✓ Paliperidone: 12-17 years for Schizophrenia.
 - ✓ Risperidone (oral only): ≥ 5 years for irritability associated with Autistic disorder; ≥ 10 years for Bipolar I disorder; ≥ 13 years for Schizophrenia.
 - ✓ Quetiapine (regular-release tablets): 10-17 years for Bipolar disorder; 13-17 years for Schizophrenia.



Antidepressants & Antianxiety Medications

- ✓ Amitriptyline: ≥ 12 years for Major depressive disorder.
- ✓ Amoxapine: ≥ 16 years for Major depressive disorder.
- ✓ Clomipramine: ≥ 10 years for Obsessive-compulsive disorder.
- ✓ Doxepin: ≥ 12 years for Depression, Alcoholism, Anxiety, Psychoneurotic personality disorder.
- ✓ Escitalopram: ≥ 12 years for Major depressive disorder.
- ✓ Fluoxetine: ≥ 7 years for Obsessive-compulsive disorder; ≥ 8 years for Major depressive disorder.




Antidepressants & Antianxiety Medications

- ✓ Fluvoxamine (immediate-release formulation only): ≥ 8 years for Obsessive-compulsive disorder.
- ✓ Hydroxyzine Hydrochloride: Age not specified, for Anxiety, Psychomotor agitation (intramuscular only), Sedation (oral only).
- ✓ Imipramine: ≥ 6 years for Bedwetting.
- ✓ Isocarboxazid: ≥ 16 years for Major depressive disorder.
- ✓ Oxazepam: ≥ 6 years for Anxiety, Alcohol withdrawal syndrome.
- ✓ Sertraline: ≥ 6 years for Obsessive-compulsive disorder.
- ✓ Trimipramine: ≥ 12 years for Major depressive disorder.



Sleep disorder agents

- ✓ Diphenhydramine: ≥ 12 years for Insomnia.
 - ✓ Flurazepam: ≥ 15 years for Insomnia.
 - ✓ Hydroxyzine Hydrochloride: Age not specified, for Anxiety, Psychomotor agitation (intramuscular only), Sedation (oral only).
 - ✓ Lorazepam: ≥ 12 years (oral only) for Insomnia, due to anxiety or situational stress; Anxiety.
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Mood Stabilizers and Anticonvulsants

- ✓ Lithium: ≥ 12 years for Bipolar disorder.
- ✓ Valproic Acid: ≥ 10 years for seizures.
- ✓ Carbamazepine: Any age for Epilepsy, Partial, generalized, and mixed types.
- ✓ Gabapentin: 3-12 years for Partial seizure.
- ✓ Lamotrigine: immediate-release ≥ 2 years for Partial seizure; Tonic-clonic seizure, Primary generalized; extended-release only ≥ 13 years for Partial seizure; Tonic-clonic seizure, Primary generalized; ≥ 2 years for Lennox-Gastaut syndrome.



Anticonvulsants(continued)

- ✓ Oxcarbazepine: ≥ 2 years for Partial seizure, Adjunct; ≥ 4 years for Partial seizure, monotherapy.
 - ✓ Topiramate: ≥ 2 years for Lennox-Gastaut syndrome; Partial seizure; Tonic-clonic seizure, Primary generalized.
 - ✓ Ethosuximide: ≥ 3 years for Absence seizure.
 - ✓ Ethotoin : Any age for Complex partial epileptic seizure, Grand mal seizure.
 - ✓ Levetiracetam: ≥ 12 years (oral) and ≥ 16 years (IV) for Myoclonic seizure; ≥ 4 years (oral solution and immediate-release tablets) and ≥ 16 years (extended-release tablets and IV) for Partial seizure; ≥ 6 years (oral) and ≥ 16 years (IV) for Tonic-clonic seizure, primary generalized.
 - ✓ Mephobarbital: Age not specified, for seizure.
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Anticonvulsants (continued)

- ✓ Methsuximide: Age not specified, for Absence seizure, Refractory.
- ✓ Phenobarbital: Age not specified, for Epilepsy, Sedation.
- ✓ Phenytoin: Age not specified, for seizure, during and following neurosurgery; Generalized tonic-clonic and Complex partial seizures.
- ✓ Primidone: Age not specified, for Epilepsy, monotherapy or adjunct.
- ✓ Tiagabine: ≥ 12 years for Partial seizure, adjunct.
- ✓ Zonisamide: ≥ 16 years for Partial seizure.



Tics/Tourette syndrome agents

- ✓ Pimozide: ≥ 12 years in patients who have failed to adequately respond to standard treatment.
- ✓ Haloperidol: ≥ 3 years, oral only.



Nocturnal enuresis agents

- ✓ Imipramine: ≥ 6 years.
- ✓ Desmopressin Acetate: ≥ 6 years.



Miscellaneous agents

- ✓ Amantadine: ≥ 1 year for prophylaxis of influenza.
- ✓ Chlordiazepoxide: ≥ 6 years for Anxiety about treatment, Preoperative.
- ✓ Benztropine: ≥ 3 years for Extrapyrarnidal disease - Medication-induced movement disorder.
- ✓ Bromocriptine: ≥ 16 years for Prolactinoma.
- ✓ Cyproheptadine: Age not specified, for Allergic conjunctivitis; Allergic rhinitis; Anaphylaxis, Adjunct; Dermatographic urticaria; Immune hypersensitivity reaction, to blood or plasma, or mild allergic skin manifestations; Urticaria due to cold; Vasomotor rhinitis.
- ✓ Dantrolene: Age not specified for Malignant hyperthermia; ≥ 5 years for Malignant hyperthermia, Post-crisis follow-up, Prophylaxis; Spasticity, chronic.



Miscellaneous agents (continued)

- ✓ **Docusate:** Age not specified, for Congenital hypothyroidism; Hypothyroidism; Myxedema; Simple goiter; Thyroid uptake with thyroid suppression.
- ✓ **Metoclopramide:** Age not specified, for Constipation care.
- ✓ **Flumazenil:** ≥ 1 year for Reversal of benzodiazepine activity.
- ✓ **Levothyroxine:** Age not specified, for Hypothyroidism, Myxedema coma.
- ✓ **Liothyronine :** Age not specified for Intestinal intubation, small bowel.



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Answers

- 1) D
- 2) B
- 3) C