

# Focalin

**Generic Name:** [dexamethylphenidate](#) (dex METH il FEN i date)

**Brand Name:** *Focalin, Focalin XR*

## What is Focalin?

Focalin (dexamethylphenidate) is a mild stimulant to the central nervous system. It affects chemicals in the brain that contribute to hyperactivity and impulse control.

Focalin is used to treat attention deficit hyperactivity disorder (ADHD).

Focalin may also be used for purposes not listed in this medication guide.

## Important information

You should not use Focalin if you have glaucoma, tics or Tourette's syndrome, or severe anxiety, tension, or agitation.

Do not use Focalin if you have taken an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, tranylcypromine, and others.

Focalin may be habit forming. **Never share this medicine with another person, especially someone with a history of drug abuse or addiction.** Keep Focalin in a place where others cannot get to it.

## Before taking this medicine

Do not use Focalin if you have taken an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, tranylcypromine, and others.

You should not take Focalin if you are allergic to dexamethylphenidate or methylphenidate (Ritalin, Concerta), or if you have:

- glaucoma;
- a personal or family history of tics (muscle twitches) or Tourette's syndrome; or
- if you have significant tension, agitation, or anxiety.

**Some stimulants have caused sudden death in people with serious heart problems or congenital heart defects.** Tell your doctor if you have:

- heart disease, heart rhythm disorder;
- coronary artery disease (hardened arteries); or
- history of heart attack.

To make sure this medicine is safe for you, tell your doctor if you have:

- high blood pressure;
- a personal or family history of mental illness, psychotic disorder, bipolar illness, depression, or suicide attempt;
- peripheral vascular disease such as Raynaud's syndrome;
- epilepsy or other seizure disorder;
- tics (muscle twitches) or Tourette's syndrome; or
- a history of drug or alcohol addiction.

Focalin may be habit forming. **Never share this medicine with another person, especially someone with a history of drug abuse or addiction.**

FDA pregnancy category C. It is not known whether Focalin will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medication.

It is not known whether dextmethylphenidate passes into breast milk or if it could harm a nursing baby. Tell your doctor if you are breast-feeding a baby.

Long-term use of Focalin can slow a child's growth. Tell your doctor if the child using this medication is not growing or gaining weight properly.

Do not give this medicine to a child younger than 6 years old without medical advice.

## How should I take Focalin?

Take Focalin exactly as prescribed by your doctor. Follow all directions on your prescription label. Your doctor may occasionally change your dose to make sure you get the best results. Do not take this medicine in larger or smaller amounts or for longer than recommended.

You may take Focalin with or without food.

To make swallowing easier, you may open the Focalin capsule and sprinkle the medicine into a spoonful of applesauce. Swallow right away without chewing. Do not save the mixture for later use.

Your doctor will need to check your progress while you are using this medicine.

Store at room temperature away from moisture and heat.

Keep track of the amount of medicine used from each new bottle. Focalin is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

## What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid?

Avoid taking Focalin in the evening because it may cause sleep problems (insomnia).

This medication may cause blurred vision and may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert and able to see clearly.

## Focalin side effects

Get emergency medical help if you have any of these **signs of an allergic reaction to Focalin**: fever; hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Stop taking Focalin and call your doctor at once if you have:

- mood swings, aggression, hostility, confusion, hallucinations, unusual thoughts or behavior, muscle twitches;
- numbness, pain, cold feeling, unexplained wounds, or skin color changes (pale, red, or blue appearance) in your fingers or toes;
- chest pain, pounding heartbeats or fluttering in your chest, feeling like you might pass out;
- sudden numbness or weakness (especially on one side of the body), sudden severe headache, slurred speech, problems with vision or balance;
- blurred vision or other visual changes;
- seizure (convulsions);
- penis erection that is painful or lasts 4 hours or longer (rare); or
- dangerously high blood pressure (severe headache, buzzing in your ears, uneven heartbeats).

Common Focalin side effects may include:

- loss of appetite, weight loss;

- mild fever; or
- nausea, stomach pain.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## **Focalin dosing information**

### **Usual Adult Dose for Attention Deficit Disorder:**

Extended-release:

Patients currently not involved in treatment with dexamethylphenidate, racemic methylphenidate, or other stimulants:

Initial: 10 mg once a day (in the morning)

Maintenance: Dosage may be adjusted in 10 mg increments at approximately weekly intervals.

Maximum dose: 40 mg/day

Patients currently involved in treatment with methylphenidate:

Initial: one-half the total daily dose of racemic methylphenidate

Maximum dose: 40 mg/day

Patients currently taking Focalin immediate-release:

Initial dose: dose equal to the daily dose of immediate-release administered once a day (in the morning).

Maximum dose: 40 mg/day

### **Usual Pediatric Dose for Attention Deficit Disorder:**

Immediate-release:

6 to 18 years:

Patients not currently taking racemic methylphenidate or other stimulants:

Initial: 2.5 mg twice a day, with an interval of at least 4 hours between doses.

Maintenance: Dosage may be adjusted in 2.5 to 5 mg increments at approximately weekly intervals.

Maximum dose: 10 mg twice a day

Patients currently taking methylphenidate:

Initial: one-half the dose of racemic methylphenidate.

Maximum dose: 10 mg twice a day.

Extended-release:

6 to 18 years:

Patients not currently taking dexamethylphenidate, racemic methylphenidate, or other stimulants:

Initial: 5 mg once a day (in the morning)

Maintenance: Dosage may be adjusted in 5 mg increments at approximately weekly intervals.

Maximum dose: 30 mg per day

Patients currently taking methylphenidate:

Initial: one-half the dose of racemic methylphenidate.

Maximum dose: 30 mg per day

Patients currently taking Focalin immediate-release:

Initial dose: dose equal to the daily dose of immediate-release administered once a day (in the morning).

Maximum dose: 30 mg per day

## **What other drugs will affect Focalin?**

Tell your doctor about all medicines you use, and those you start or stop using during your treatment with Focalin, especially:

- an antacid;
- an antidepressant;
- blood pressure medication;
- a blood thinner (warfarin, Coumadin);
- cold or allergy medicine that contains a decongestant; or
- seizure medication.

This list is not complete. Other drugs may interact with Focalin, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

## **Where can I get more information?**

- Your pharmacist can provide more information about Focalin.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Focalin only for the indication prescribed.
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