



Focalin and Focalin XR (dexmethylphenidate)

Generic name: Dexmethylphenidate

Available strengths: 2.5 mg, 5 mg, 10 mg tablets;
5 mg, 10 mg, 15 mg, 20 mg capsules (Focalin XR)

Available in generic: No

Drug class: Stimulant

General Information

Focalin (dexmethylphenidate) and **Focalin XR (extended release)** are psychostimulants, or better known as stimulants. Focalin is used primarily in treating attention-deficit/hyperactivity disorder (ADHD) and narcolepsy, a condition characterized by daytime somnolence in which the patient periodically falls into a deep sleep during the day. Narcolepsy is a disorder of the sleep-wake control mechanisms within the brain that interferes with both daytime wakefulness and nighttime sleep.

The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments.

In numerous clinical studies and substantial clinical experience, Focalin has clearly demonstrated improvement in outcome for children with ADHD. Focalin increases the child’s ability to concentrate, extends attention span, and decreases hyperactivity. Adults with ADHD also benefit from therapy with Focalin. Focalin helps them concentrate and remain focused on tasks, increases their attention span, and decreases impulsivity and hyperactivity.

Focalin (dexmethylphenidate) is chemically similar to Ritalin (methylphenidate). Methylphenidate has two mirror-image forms, which are called **isomers** (*d*-, *l*-isomers). Focalin is the active isomer (*d*-isomer) of methylphenidate, whereas the *l*-isomer has little or no activity. Isomers are mirror-image chemicals, similar to right and left hands, and are not superimposable (i.e., cannot be placed over each other). The advantage of Focalin is that the patient is taking the active isomer of methylphenidate, but at equivalent dosages, there is little difference between Focalin and Ritalin.

Because Focalin and Focalin XR are stimulants, they are closely regulated controlled substances. The physician must write a new prescription each time they are dispensed, and a prescription cannot be refilled.

Dosing Information

The recommended starting dosage of Focalin for individuals who are not currently taking methylphenidate (Ritalin, Metadate) is 2.5 mg two times a day (5 mg/day). The dosage is adjusted in 2.5- to 5-mg daily increments

at weekly intervals to a maximum of 10 mg twice daily (20 mg/day). Focalin XR can be given once a day. Focalin may be switched to the XR formulation with an equivalent daily dose. Instead of taking Focalin 2.5 mg two times a day, for example, it may be more convenient to take Focalin XR 5 mg once a day in the morning. Focalin XR 5 mg, 10 mg, 15 mg, and 20 mg are equivalent to Focalin 2.5 mg, 5 mg, 7.5, and 10 mg twice a day. For individuals currently taking methylphenidate and switching to Focalin or Focalin XR, the starting dosage is half the dosage of methylphenidate.

The dosing of Focalin in adults is based on clinical presentation and individualized to the patient's response and report of side effects. In children, dosing is also based on age and weight. The other consideration in dosing is selection of a formulation with the duration of action tailored to the needs of the patient. Focalin is short acting and begins to work in 30–60 minutes after administration, with duration of 2–5 hours. The advantage is that it works quickly, but the duration of action is short and requires dosing two or three times a day.

Common Side Effects

The common side effects associated with taking Focalin are rapid heart rate, palpitations, nervousness, restlessness, insomnia, dry mouth, constipation, nausea, diarrhea, loss of appetite, weight loss, and elevation of blood pressure.

Adverse Reactions and Precautions

Focalin has a high potential for abuse. Individuals with a history of alcohol and substance abuse may be at risk for abusing stimulants. Individuals who abuse Focalin develop tolerance and psychological dependence that may result in addiction. With long-term abuse of Focalin and the resulting sleepless nights, the individual may develop psychotic symptoms.

Focalin may increase blood pressure. Individuals with a history of high blood pressure or heart disease should be cautious about taking Focalin because it can exacerbate these conditions. Uncontrolled high blood pressure can have serious consequences, including stroke and heart attack. Patients taking Focalin should routinely check their blood pressure.

Individuals with a history of seizure disorder should be cautious while taking Focalin, because it can lower the seizure threshold and increase susceptibility for seizures.

In children and adolescents who are still in their growth period, Focalin can suppress linear growth. Physicians commonly interrupt treatment on weekends and holidays when children are not in school, for growth catch-up. Children and adolescents taking Focalin require close monitoring for growth suppression and periodic measuring of their height. This effect is not a concern in the adult population.

Focalin may make tics worse in individuals with a tic disorder (i.e., twitching of a muscle group, especially in the face).

Focalin should be avoided, or used with caution, by patients with a diagnosis of schizophrenia or bipolar disorder. Stimulants are frequently abused in this population, and high doses of Focalin may trigger psychosis and mania.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Focalin has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. Women who are pregnant or may become pregnant should discuss this with their physician.

Nursing mothers should not take any stimulant, because small amounts will pass into breast milk and be ingested by the baby. If stopping the stimulant is not an alternative, breastfeeding should not be started or should be discontinued.

Possible Drug Interactions

Focalin should not be taken in combination with a group of antidepressants known as **monoamine oxidase inhibitors** (MAOIs). The combination may precipitate increases in blood pressure. This and other significant drug interactions reported with amphetamine and methylphenidate are summarized in the table below.

Monoamine oxidase inhibitors (MAOIs) (e.g., Parnate, Emsam, Nardil, Marplan)	MAOIs should not be taken with methylphenidates or dexmethylphenidate (e.g., Concerta, Ritalin, Focalin). The combination may precipitate dangerous elevation of blood pressure.
Weight-loss medications (e.g., Meridia)	Weight-loss medications, prescription and non-prescription, should not be taken with methylphenidates or dexmethylphenidate. The combination may increase blood pressure or cause irritability, insomnia, and other adverse reactions from excessive stimulation.
Coumadin (warfarin)	Methylphenidate and dexmethylphenidate may increase the anticoagulant action of Coumadin.

Overdose

The severity of Focalin overdose depends on the amount ingested. The individual may experience a progression of the following symptoms from an acute overdose: restlessness, agitation, irritability, insomnia, hyperactivity, confusion, elevated blood pressure, rapid heart rate, delirium, hallucinations, irregular heart beat, convulsions, coma, circulatory collapse, and death.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency room for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

Special Considerations

- To avoid insomnia, the last daily dose of Focalin should be taken early in the evening, and not close to bed-time.
- Focalin may be taken with food to avoid stomach upset.
- Do not take more than instructed by your physician.
- If Focalin causes pronounced nervousness, restlessness, insomnia, loss of appetite, or weight loss, notify your physician.
- If you miss a dose, take it as soon as possible. If it is close to the next scheduled dose, skip the missed dose and continue on your regular dosing schedule. Do not take double doses.

- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication, and the medication may lose its therapeutic effects.
- Keep your medication out of reach of children.

If you have any questions about your medication, consult your physician or pharmacist.

Notes

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