



Metadate-ER/Metadate-CD (methylphenidate, extended release)

Generic name: Methylphenidate, extended release

Available strengths: 10 mg, 20 mg extended-release tablets (Metadate ER);

10 mg, 20 mg, 30 mg extended-release capsules (Metadate-CD)

Available in generic: No, only immediate-release methylphenidate

Drug class: Stimulant

General Information

Metadate ER and **Metadate-CD (methylphenidate, extended release)** are psychostimulants, or better known as stimulants. Metadate 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 indication 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 these medications for these unapproved indications. Metadate is often used to augment antidepressants in treating refractory depression. For patients with chronic treatment-resistant depression, for example, Metadate in combination with antidepressants can provide symptomatic relief and improvement beyond that experienced with antidepressants alone.

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

Metadate-ER incorporates methylphenidate in an extended-release tablet composed of a wax matrix, allowing slow release of the stimulant as the tablet passes through the gastrointestinal tract. The -ER tablet has duration of approximately 8 hours, and a single tablet provides a duration of effect corresponding to the total daily dosage of immediate-release methylphenidate. The disadvantage of the -ER tablet is that it takes about

2–3 hours before peak clinical effects are seen, which may be problematic, especially for school-age children. Metadate-CD, a dual-action preparation, overcomes this drawback. Metadate-CD provides immediate and extended release of the stimulant. The -CD capsules contain methylphenidate incorporated into two types of beads: one type releases the medication immediately after ingestion, while a second set of beads provides sustained release of methylphenidate lasting up to 8 hours. The immediate-release beads account for about 30% of the total methylphenidate in the capsule. From a single dose of Metadate-CD taken early in morning, there is an initial release of methylphenidate followed by sustained release throughout the afternoon. By evening, the methylphenidate in the body decreases, so that by bedtime the medication should not interfere with sleep.

Dosing Information

For adults, the usual starting dosage for immediate-release methylphenidate is 5 mg twice a day and is adjusted on the basis of the individual's response. The average dosage is 20–30 mg/day, administered two or three times daily. The maximum dosage should not exceed 60 mg/day. Metadate-ER may be used in place of regular methylphenidate by replacing the total daily dosage of methylphenidate with an equivalent dosage of Metadate-ER. For example, the dosage of an individual taking 10 mg of methylphenidate twice daily could be switched to 20 mg of Metadate-ER once a day in the morning. The -ER tablets should be swallowed whole and not chewed or crushed.

Individuals new to methylphenidate may initially take 10–20 mg of Metadate-CD in the morning, and the dosage may be increased in weekly intervals by 10 mg, based on response, up to a maximum dosage of 60 mg/day. For individuals currently taking regular methylphenidate or Metadate-ER, the previous daily dosage may be converted to the nearest dosage of Metadate-CD. For example, the dosage of an individual taking 5 mg three times a day (15 mg/day) of regular methylphenidate could be converted to 20 mg of Metadate-CD once a day. Metadate-ER could be substituted with an equivalent dose of Metadate-CD.

Metadate tablets and capsules should be swallowed whole and not chewed or crushed. The -CD capsules may be opened and sprinkled over a spoonful of applesauce and swallowed without chewing.

Common Side Effects

The common side effects associated with taking Metadate 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

Metadate 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 Metadate develop tolerance and psychological dependence that may result in addiction. With long-term abuse of Metadate and the resulting sleepless nights, the individual may develop psychotic symptoms.

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

Individuals with a history of seizure disorder should be cautious while taking Metadate because it can lower the seizure threshold.

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

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

Metadate 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 stimulants may trigger psychosis and mania.

Possible Drug Interactions

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

Ismelin (guanethidine)	The antihypertensive effects of Ismelin (i.e., lowering of blood pressure) may be decreased when combined with Metadate.
Monoamine oxidase inhibitors (MAOIs)	MAOI antidepressants (e.g., Parnate) should not be taken with Metadate; the combination may precipitate dangerous elevation of blood pressure.
Selective serotonin reuptake inhibitors (SSRIs)	Metadate and other stimulants may elevate the blood levels of SSRI antidepressants (e.g., Paxil, Prozac) and enhance their effects.
Weight-loss medications	Weight-loss medications, prescription and non-prescription, should not be taken with stimulants. Excess stimulation may cause agitation, irritability, insomnia, and other adverse reactions.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Metadate 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.

Overdose

The severity of acute Metadate 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 department 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

- The last daily dose of Metadate should be taken early in the evening, and not close to bedtime, to avoid insomnia.
- Metadate may be taken at mealtime or with food to avoid stomach upset.
- Do not take more than instructed by your physician.
- If Metadate 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 late in the afternoon or evening, skip your dose of Metadate-ER or -CD and continue your regular dosing schedule the next morning. Taking the long-acting stimulant late in the day may interfere with your sleep.
- Do not chew or crush the tablets or capsules; swallow them whole. Take with a full glass of water to help swallow the medication.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of the medication.
- Keep your medication out of reach of children.

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

Notes
