

Alaradate™

Methylphenidate Hydrochloride
Tablet & Oral Solution

Presentation

Alaradate™ 10: Each tablet contains Methylphenidate Hydrochloride USP 10 mg.

Alaradate™ Oral Solution: Each 5 ml solution contains Methylphenidate Hydrochloride USP 5 mg.

Description

Methylphenidate is a central nervous system (CNS) stimulant.

Indications and usage

Methylphenidate is indicated for treatment of Attention Deficit Hyperactivity Disorders (ADHD) and Narcolepsy.

Dosage and administration

- Pediatric Patients 6 years and older: Start with 5 mg twice daily (before breakfast and lunch), titrating the dose weekly in 5 to 10 mg increments. Dosages above 60 mg/day are not recommended.
- Adults: 20 to 30 mg, administered 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum total daily dosage is 60 mg. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 pm.

Adverse reactions

The most common adverse reactions of Methylphenidate are sleep disturbances, restlessness, dizziness, headache, tremor, convulsion, rash, pruritis; urticaria, fever, arthralgia, alopecia, exfoliative, dermatitis, erythema multiforme, thrombocytopenic purpura, thrombocytopenia, Leucopenia, urinary disorder and very rarely liver damage.

Contraindications

Methylphenidate is contraindicated in alcoholics, emotionally unstable patients, drug abusers, hypertension, cardiac arrhythmias, psychoses, epilepsy, thyro-toxicosis, severe depression, in patients who are undergoing treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days and known sensitivity to methylphenidate.

Precautions

Methylphenidate have a high potential for abuse and dependence. Avoid use in patients with known serious structural cardiac abnormalities, hypertension and, tachycardia, psychosis, priapism and long-term suppression of growth.

Drug interactions

Atomoxetine should be used with caution in combination with:

- Antihypertensive drugs.
- Halogenated anesthetics: Avoid use of Methylphenidate on the day of surgery if halogenated anesthetics is used.

Use in specific population

Pregnancy & Lactation: Pregnancy Category C. Adequate and well-controlled studies in pregnant women have not been conducted. It is not known whether Methylphenidate is excreted in human milk.

Pediatric use: The safety, efficacy, and pharmacokinetics of Methylphenidate in pediatric patients less than 6 years of age have not been evaluated.

Geriatric use: Methylphenidate in geriatric patients have not been evaluated.

Overdose

Signs and symptoms of acute overdosage may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hyperreflexia, muscle twitching, convulsions (which may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, hypotension, tachypnea, mydriasis and rhabdomyolysis.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

Alaradate™ 10: Each box contains 3 blister strips of 10 tablets.

Alaradate™ Oral Solution: Each bottle contains 100 ml oral solution.