

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RITALIN and RITALIN-SR safely and effectively. See full prescribing information for RITALIN and RITALIN-SR.

RITALIN® (methylphenidate hydrochloride) tablets, for oral use, CII
RITALIN-SR® (methylphenidate hydrochloride) extended-release tablets, for oral use, CII
Initial U.S. Approval: 1955

WARNING: ABUSE AND DEPENDENCE

See full prescribing information for complete boxed warning.

- CNS stimulants, including Ritalin and Ritalin-SR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence (5.1, 9.2, 9.3).
- Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy (5.1, 9.2)

RECENT MAJOR CHANGES

Boxed Warning	1/2019
Contraindications (4)	1/2019
Warnings and Precautions (5)	1/2019

INDICATIONS AND USAGE

Ritalin is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorders (ADHD) and Narcolepsy (1).

DOSAGE AND ADMINISTRATION

Ritalin Tablets (2.2):

- 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: Average daily dosage is 20 to 30 mg, administered 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum total daily dosage is 60 mg.

Ritalin-SR Extended-release Tablets (2.2):

- May switch to Ritalin-SR when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin.
- Must be swallowed whole and never crushed or chewed.

DOSAGE FORMS AND STRENGTHS

- Tablets: 5 mg, 10 mg, and 20 mg (3)
- Extended-release Tablets: 20 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other product components of Ritalin or Ritalin-SR (4).
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days (4).

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: ABUSE AND DEPENDENCE

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

- 2.1 Pretreatment Screening
- 2.2 General Dosing Information
- 2.3 Dose Reduction and Discontinuation

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Potential for Abuse and Dependence
- 5.2 Serious Cardiovascular Reactions
- 5.3 Blood Pressure and Heart Rate Increases
- 5.4 Psychiatric Adverse Reactions
- 5.5 Priapism
- 5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon
- 5.7 Long-Term Suppression of Growth

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

- 7.1 Clinically Important Interactions with Ritalin and Ritalin-SR

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy

WARNINGS AND PRECAUTIONS

- **Serious Cardiovascular Events:** Sudden death has been reported in association with CNS-stimulant treatment at usual doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm arrhythmias, or coronary artery disease (5.2).
- **Blood Pressure and Heart Rate Increases:** Monitor blood pressure and pulse. Consider the benefits and risk in patients for whom an increase in blood pressure or heart rate would be problematic (5.3).
- **Psychiatric Adverse Reactions:** Use of stimulants may cause psychotic or manic symptoms in patients with no prior history or exacerbation of symptoms in patients with preexisting psychiatric illness. Evaluate for preexisting psychotic or bipolar disorder prior to Ritalin and Ritalin-SR use (5.4).
- **Priapism:** Cases of painful and prolonged penile erections, and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed (5.5).
- **Peripheral Vasculopathy, including Raynaud's Phenomenon:** Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants (5.6).
- **Long-Term Suppression of Growth:** Monitor height and weight at appropriate intervals in pediatric patients (5.7).

ADVERSE REACTIONS

Common adverse reactions: tachycardia, palpitations, headache, insomnia, anxiety, hyperhidrosis, weight loss, decreased appetite, dry mouth, nausea, and abdominal pain (6).

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Antihypertensive drugs: Monitor blood pressure. Adjust dosage of antihypertensive drug as needed (7).
- Halogenated anesthetics: Avoid use of Ritalin or Ritalin-SR on the day of surgery if halogenated anesthetics will be used (7).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2019

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

9.2 Abuse

9.3 Dependence

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.