Ritalin/Ritalin SR (methylphenidate hydrochloride) - Drug Summary

Novartis Pharmaceuticals Corporation

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Ritalin
(methylphenidate hydrochloride)

BOXED WARNING

Caution w/ history of drug dependence or alcoholism. Chronic abuse may lead to marked tolerance and psychological dependence w/ varying degrees of abnormal behavior. Frank psychotic episodes may occur, especially w/ parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic use may unmask symptoms of underlying disorder that may require follow-up.

COMMON BRAND NAMES

Ritalin-SR, Ritalin

THERAPEUTIC CLASS

CNS stimulant

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Attention Deficit Disorders

Tab:
20-30mg/day given in divided doses bid-tid, preferably 30-45 min ac; some patients may require 40-60mg/day and others, 10-15mg/day may be adequate
Last dose should be taken before 6 pm if patient is unable to sleep as a result of taking medication late in the day

Tab, Sustained-Release (SR):
May be used in place of methylphenidate immediate-release (IR) tabs when the 8-hr dosage of SR tab corresponds to the titrated 8-hr dosage of methylphenidate IR tabs

Narcolepsy

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20-30mg/day given in divided doses bid-tid, preferably 30-45 min ac; some patients may require 40-60mg/day and others, 10-15mg/day may be adequate
Last dose should be taken before 6 pm if patient is unable to sleep as a result of taking medication late in the day

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PEDIATRIC DOSAGE & INDICATIONS

Attention Deficit Disorders

≥6 Years:
Tab:
Initial: 5mg bid before breakfast and lunch
Titrate: Increase gradually by 5-10mg weekly
Max: 60mg/day

Tab, Sustained-Release (SR):
May be used in place of methylphenidate immediate release (IR) tabs when the 8-hr dosage of SR tab corresponds to the titrated 8-hr dosage of methylphenidate IR tabs

D/C if no improvement seen after appropriate dosage adjustment over 1 month
D/C periodically to assess the child's condition; therapy should not be indefinite

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DOSING CONSIDERATIONS

Adverse Reactions
Children ≥6 Years:
Reduce dose or, if necessary, d/c if paradoxical aggravation of symptoms or other adverse effects occur

ADMINISTRATION

Oral route

Tab, SR
Swallow tabs whole; do not crush or chew.

HOW SUPPLIED

Tab: (Ritalin) 5mg, 10mg*, 20mg*; **Tab, SR:** (Generic) 10mg, (Ritalin-SR) 20mg *scored

CONTRAINDICATIONS

Marked anxiety, tension, agitation, glaucoma, motor tics or family history or diagnosis of Tourette's syndrome. Treatment w/ MAOIs or w/in a minimum of 14 days following discontinuation of an MAOI.

WARNINGS/PRECAUTIONS

Avoid w/ known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Sudden death reported in children and adolescents w/ structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and MI reported in adults. May increase BP and HR; caution w/ conditions that may be compromised by increases in BP/HR (eg, preexisting HTN, heart failure, recent MI). Prior to treatment, obtain medical history (including assessment for family history of sudden death or ventricular arrhythmia) and perform a physical exam to assess for the presence of cardiac disease. Promptly perform cardiac evaluation if symptoms of cardiac disease develop. May exacerbate symptoms of behavior disturbance and thought disorder in patients w/ preexisting psychotic disorder. Caution in patients w/ comorbid bipolar disorder; may induce mixed/manic episode. May cause treatment-emergent psychotic or manic symptoms (eg, hallucinations, delusional thinking, mania) in children and adolescents w/o prior history of psychotic illness or mania; consider discontinuation if such symptoms occur. Aggressive behavior or hostility reported in children and adolescents. May cause long-term suppression of growth in children; monitor growth, and may need to interrupt treatment in patients not growing or gaining height or weight as expected. May lower convulsive threshold; d/c if seizures occur. Priapism, sometimes requiring surgical intervention, reported. Associated w/ peripheral vasculopathy, including Raynaud's phenomenon. Difficulties w/ accommodation and blurring of vision reported. Patients w/ an element of agitation may react adversely; d/c if necessary.

ADVERSE REACTIONS

Nervousness, insomnia, hypersensitivity reactions, anorexia, nausea, dizziness, palpitations, headache, dyskinesia, drowsiness, BP and pulse changes, tachycardia, angina, cardiac arrhythmia, abdominal pain.

DRUG INTERACTIONS

See Contraindications. Caution w/ pressor agents. May decrease effectiveness of drugs used to treat HTN. May inhibit metabolism of coumarin anticoagulants, anticonvulsants (eg, phenobarbital, phenytoin, primidone), and TCAs (eg, imipramine, clomipramine, desipramine); downward dose adjustment and monitoring of plasma drug concentration (or coagulation times for coumarin) of these drugs may be necessary when initiating or discontinuing methylphenidate.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Caution in nursing.

MECHANISM OF ACTION

Mild CNS stimulant; has not been established. Thought to activate the brain stem arousal system and cortex to produce its stimulant effect.

PHARMACOKINETICS

Absorption: (Children) T_{max}=4.7 hrs (Tab, SR), 1.9 hrs (Tab). **Metabolism:** Deesterification to α-phenyl-2-

piperidine acetic acid (ritalinic acid) (major metabolite). **Elimination:** Urine (Tab, SR) (86%; 67% [Children]).

ASSESSMENT

Assess for hypersensitivity to the drug, marked anxiety, tension, agitation, glaucoma, motor tics or family history or diagnosis of Tourette's syndrome, cardiovascular conditions, history of drug dependence or alcoholism, psychotic disorder, comorbid bipolar disorder, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for changes in HR and BP, signs/symptoms of cardiac disease, exacerbation of behavior disturbance and thought disorder, psychosis, mania, appearance of or worsening of aggressive behavior or hostility, seizures, priapism, digital changes, visual disturbances, and other adverse reactions. In pediatric patients, monitor growth. Perform periodic monitoring of CBC, differential, and platelet counts during prolonged therapy.

PATIENT COUNSELING

Inform about the benefits and risks of therapy and counsel about appropriate use. Instruct to seek immediate medical attention in the event of priapism. Instruct to report to physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes, and to contact physician immediately if any signs of unexplained wounds appear on fingers or toes while taking the drug.

STORAGE

Ritalin/Ritalin-SR: 25°C (77°F); excursions permitted to 15-30°C (59-86°F). **Generic:** 20-25°C (68-77°F). **Tab:** Protect from light. **Tab, SR:** Protect from moisture.

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