# Concerta (methylphenidate hydrochloride) - Drug Summary

Janssen Pharmaceuticals, Inc.





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Concerta
(methylphenidate hydrochloride)

## BOXED WARNING

Caution w/ history of drug dependence or alcoholism. Chronic abusive use 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.

## THERAPEUTIC CLASS

CNS stimulant

## DEA CLASS

CII

## ADULT DOSAGE & INDICATIONS

### Attention-Deficit Hyperactivity Disorder

**18-65 Years:**
**New to Methylphenidate:**
**Initial:** 18mg or 36mg qam
**Range:** 18-72mg/day

**Currently on Methylphenidate:**
**Initial:**
18mg qam if previous dose 5mg bid-tid
36mg qam if previous dose 10mg bid-tid
54mg qam if previous dose 15mg bid-tid
72mg qam if previous dose 20mg bid-tid
Conversion dosage should not exceed 72mg/day

**Titrate:** May increase in 18mg increments at weekly intervals if optimal response is not achieved at a lower dose

**Max:** 72mg/day

**Maint/Extended Treatment:**
Periodically reevaluate the long-term usefulness of the drug

D/C if no improvement observed after appropriate dosage adjustment over 1 month

## PEDIATRIC DOSAGE & INDICATIONS

### Attention-Deficit Hyperactivity Disorder

**New to Methylphenidate:**
**6-12 Years:**
**Initial:** 18mg qam
**Range:** 18-54mg/day

**13-17 Years:**
**Initial:** 18mg qam
**Range:** 18-72mg/day not to exceed 2mg/kg/day

**Currently on Methylphenidate:**

**≥6 Years:**
**Initial:**
18mg qam if previous dose 5mg bid-tid
36mg qam if previous dose 10mg bid-tid
54mg qam if previous dose 15mg bid-tid
72mg qam if previous dose 20mg bid-tid
Conversion dosage should not exceed 72mg/day

**Titrate:** May increase in 18mg increments at weekly intervals if optimal response is not achieved at a lower dose

**Max:**
**6-12 Years:** 54mg/day
**13-17 Years:** 72mg/day

**Maint/Extended Treatment:**
Periodically reevaluate the long-term usefulness of the drug

D/C if no improvement observed after appropriate dosage adjustment over 1 month

## DOSING CONSIDERATIONS

**Adverse Reactions**
Reduce dose or, if necessary, d/c if paradoxical aggravation of symptoms or other adverse events occur

## ADMINISTRATION

Oral route

Take w/ or w/o food
Swallow tab whole w/ the aid of liquids; do not chew, divide, or crush

## HOW SUPPLIED

Tab, Extended-Release: 18mg, 27mg, 36mg, 54mg

## 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 deaths, stroke, and MI reported in adults. May increase BP and HR; caution w/ conditions that might be compromised by increases in BP/HR (eg, preexisting HTN, heart failure, recent MI, ventricular arrhythmia). Prior to treatment, obtain medical history (including assessment for family history of sudden death or ventricular arrhythmia) and perform physical exam to assess for 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 patients w/o prior history of psychotic illness or mania; consider discontinuation if such symptoms occur. Aggressive behavior or hostility reported. May lower convulsive threshold; d/c if seizures occur. Priapism reported; seek immediate medical attention if abnormally sustained or frequent and painful erections develop. Associated w/ peripheral vasculopathy (eg, Raynaud's phenomenon); carefully observe for digital changes. 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. Difficulties w/ accommodation and blurring of vision reported. Tab is nondeformable and does not appreciably change in shape in the GI tract; avoid w/ preexisting severe GI narrowing (pathologic or iatrogenic).

## ADVERSE REACTIONS

Decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, decreased weight, irritability, upper abdominal pain, hyperhidrosis, palpitations, tachycardia, depressed mood, nervousness.

## DRUG INTERACTIONS

See Contraindications. Caution w/ vasopressor agents. May inhibit metabolism of coumarin anticoagulants, anticonvulsants (eg, phenobarbital, phenytoin, primidone), and some antidepressants (eg, TCAs, SSRIs); downward dose adjustment and monitoring of plasma drug concentrations (or coagulation times for coumarin) of these drugs may be necessary when initiating or discontinuing methylphenidate.

## PREGNANCY AND LACTATION

Category C, caution in nursing.

## MECHANISM OF ACTION

Sympathomimetic amine; CNS stimulant. Has not been established; thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

## PHARMACOKINETICS

**Absorption:** Readily absorbed. $T_{max}$=6-10 hrs. (Single-dose [18mg qd]) AUC=41.8ng•hr/mL; $C_{max}$=3.7ng/mL. **Metabolism:** Via deesterification; α-phenyl-piperidine acetic acid [PPAA] (metabolite). **Elimination:** Urine (90%, approx 80% PPAA); $T_{1/2}$=3.5 hrs.

## ASSESSMENT

Assess for hypersensitivity to the drug, marked anxiety, tension, agitation, glaucoma, motor tics, family history or diagnosis of Tourette's syndrome, cardiovascular conditions, history of drug dependence or alcoholism, psychotic disorder, comorbid bipolar disorder, severe GI narrowing, 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, peripheral vasculopathy (eg, Raynaud's phenomenon), visual disturbances, and other adverse reactions. In pediatric patients, monitor growth. Perform periodic monitoring of CBC, differential, and platelet counts during prolonged therapy. Periodically reevaluate long-term usefulness of drug.

## PATIENT COUNSELING

Inform about risks, benefits, and appropriate use of the medication. Advise of the possibility of priapism; instruct to seek immediate medical attention in the event of priapism. Inform about the risk of peripheral vasculopathy (eg, Raynaud's phenomenon); instruct to report to physician any new numbness, pain, skin color change, sensitivity to temperature in fingers or toes, or any signs of unexplained wounds appearing on fingers/toes. Advise that the tab shell, along w/ insoluble core components, is eliminated from the body; inform not to be concerned if something that looks like a tab is noticed in the stool. Inform that therapy may impair mental/physical abilities; advise to use caution w/ hazardous tasks (eg, operating machinery, driving).

## STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from humidity.

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