

CONCERTA[®] EXTENDED RELEASE TABLETS

Methylphenidate hydrochloride (18mg, 27mg, 36mg)

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What CONCERTA[®] is used for

CONCERTA[®] is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents aged 6 to 17 and adults aged 18 to 65 years old.

How CONCERTA[®] works

CONCERTA[®] improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behavior.

The medicine is given as part of a treatment program, which usually includes:

- psychological
- education and
- social therapy

Although there is no cure for ADHD, it can be managed using treatment programs.

Before you use CONCERTA[®]

- *When you must not use it*

You should not take CONCERTA[®] if you:

- Are allergic to methylphenidate or any of the other ingredients in CONCERTA[®] (see **Product Description**).
- Are being treated or recently been treated with monoamine oxidase (MAO) inhibitor medicines within 14 days.
- Take CONCERTA[®] for severe depression and/or for the prevention or treatment of normal fatigue states.

- Use in children under 6 years old.

- *Before you start to use it*

Talk to your doctor *before* or while taking CONCERTA[®] if you:

- Have a heart defect.
- Have medical conditions related to blood pressure and heart rate
- Have tics (movements or sounds that you cannot control) or Tourette's syndrome, or if someone in your family has tics or Tourette's syndrome.
- Have a serious mental health problem.
- Have history of seizures.
- Have a problem with the blood vessels in your brain (such as an aneurysm).
- Develop severe headaches, weakness or paralysis of any body part, or develop problems with coordination, vision, speaking, finding words or with your memory.
- Have a history of drug dependence or alcoholism.
- Have a narrowing or blockage of the gastrointestinal tract (esophagus, stomach, or small or large intestine).
- Have liver or kidney impairment
- Have difficulty in swallowing
- Are not growing as expected for your age. Your doctor may carefully watch your height and weight.
- Have eye problems such as increased pressure in the eye, a condition called "glaucoma", or long-sightedness (difficulty seeing near objects)

Pregnancy

If you are pregnant or planning to become pregnant, you should inform your doctor, who will decide if you can take CONCERTA[®].

Breastfeeding

Tell your doctor if you are breastfeeding. Methylphenidate passes into breast milk; your doctor will decide if you can take CONCERTA[®].

- *Taking other medicines*

Tell your doctor about all medicines you are taking. Your doctor will decide whether you can take CONCERTA[®] with other medicines.

- CONCERTA[®] should not be used in people being treated (currently or within the previous 2 weeks) with MAO inhibitors (see **When you must not use it**).
- CONCERTA[®] should be used cautiously with vasopressor agents, a type of medicine that is used to increase your blood pressure.
- CONCERTA[®] may decrease the effectiveness of medicines called 'anti hypertensives', which are used to treat high blood pressure. Your doctor may check your blood pressure and change your dose of antihypertensive medicine.
- Tell your doctor if you are going to have an operation. CONCERTA[®] should not be taken with certain anesthetics on the day of the operation, as there is a chance of a sudden rise in blood pressure and heart rate during the operation.
- Tell your doctor if you take a type of medicine called an antipsychotic.
- CONCERTA[®] may change the way your body reacts to certain medicines. These include certain medicines used to treat depression (tricyclics and selective serotonin reuptake inhibitors), a class of medicines to prevent seizures (e.g., phenobarbital, phenytoin, primidone), or prevent blood clots (commonly called "blood thinners"). Your doctor may need to change your dose of these medicines if you are taking them with CONCERTA[®].

How to use CONCERTA[®]

- *How much to use*

Take the dose prescribed by your doctor. The doctor may adjust the amount of medicine you take until it is right for you.

- When to use it

Take CONCERTA® once each day in the morning. CONCERTA® may be taken with or without food. Swallow CONCERTA® tablets whole with water or other liquids. **Do not chew, crush or break the tablets.**

- How long to use it

Continue taking CONCERTA® for as long as your doctor recommends.

- If you forget to use it

- Consult your doctor or pharmacist on what you should do if you forget to use it.
- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Call your doctor **immediately** if you take more than the amount of CONCERTA® prescribed by your doctor.

Signs and symptoms of CONCERTA® may include the following: vomiting, feeling agitated, muscle twitching, seizures, feeling confused, seeing, feeling, hearing or smelling things that are not there (hallucinations), excessive sweating, headache, fever, fast heartbeat, feels strong pounding of heart beat, high blood pressure, dilated pupils, and dry mouth.

While you are using it

- Things you must do

- Tell your doctor if you become pregnant while taking CONCERTA®.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Never allow others to use medicines recommended for you and never use medicines prescribed for others.

- Do not be concerned if you occasionally notice in their stool something that looks like a tablet.

- Things to be careful of
Driving or Operating Machinery

- Stimulants may impair your ability to operate potentially hazardous machinery or vehicles. You should exercise caution until you are reasonably certain that CONCERTA® does not adversely affect your ability to engage in such activities.

Side effects

Like all medicines, CONCERTA® can cause side effects, although not everybody gets them.

- Very Common (may affect more than 1 in 10 people)
 - Decreased appetite;
 - Difficulty sleeping;
 - Headache;
 - Dry mouth;
 - Nausea.
- Common (may affect up to 1 in 10 people)
 - Fever, cough and sore throat;
 - Blurred vision;
 - Skin rash;
 - Cold
 - spinning sensation or dizziness;
 - Stomach pain;
 - Vomiting, diarrhea and constipation;
 - weight loss;
 - Fast or strong pounding of heart beat;
 - Hot flushes;
 - Increased blood pressure;
 - Increased level of the ‘alanine aminotransferase’ (liver enzyme) in the blood;
 - Being short of breath;
 - Shaking, muscle tightness or spasms;
 - Difficulty getting and keeping an erection (impotence);
 - Movements or sounds that you cannot control (tics);
 - Unusual feeling in the skin (such as tingling or a crawling feeling);
 - Feeling depressed, and restless;
 - Clenching or grinding the teeth;
 - Decreased sex drive;
 - Panic attacks;

- Excessive sweating and being thirsty;
- Mood swings;
- Feeling tense, confused, irritable, weak and sleepy;
- Become aggressive, anxious or agitated

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of CONCERTA®

- Storage

- Keep out of reach and sight of children.
- Store below 30°C. Keep the container tightly closed.
- Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

- Disposal

- Make a habit of returning unused or old medicines to your pharmacist.

Product description

- What it looks like

Extended-release tablets for oral use are available in the following strengths:

- 18 mg: Capsule-shaped yellow tablet with “alza 18” printed on one side in black ink
- 27 mg: Capsule-shaped gray tablet with “alza 27” printed on one side in black ink
- 36 mg: Capsule-shaped white tablet with “alza 36” printed on one side in black ink

- Ingredients

- Active ingredient
The active ingredient in CONCERTA® is methylphenidate.

- Inactive ingredients

Other inactive ingredients include butylated hydroxytoluene, carnauba wax, cellulose acetate, hypromellose, lactose, phosphoric acid, poloxamer, polyethylene glycol, polyethylene oxides, povidone, propylene glycol, sodium chloride, stearic acid, succinic acid, synthetic iron oxides, titanium dioxide, and triacetin.

- MAL number(s)

18mg - MAL05072100ARZ

27mg - MAL08061554ARZ

36mg - MAL05072101ARZ

Manufacturer

Janssen Cilag Manufacturing L.L.C
State Road 933 Km 0.1,
Mamey Ward, Gurabo,
Puerto Rico (PR)00778,
United States (USA)

Product registration holder

Johnson & Johnson Sdn Bhd (3718-D)
Level 8, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
46150, Petaling Jaya, Selangor,
Malaysia

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