PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Concerta® 18 mg, Extended-release tablets

Concerta® 27 mg, Extended-release tablets

Concerta® 36 mg, Extended-release tablets

Concerta® 54 mg, Extended-release tablets

Each **Concerta 18 mg** tablet contains
methylphenidate hydrochloride 18 mg
Each **Concerta 27 mg** tablet contains
methylphenidate hydrochloride 27 mg
Each **Concerta 36 mg** tablet contains
methylphenidate hydrochloride 36 mg
Each **Concerta 54 mg** tablet contains
methylphenidate hydrochloride 54 mg

Inactive and allergenic ingredients in the preparation - see section 6 "Further Information" and section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

WARNING: ABUSE, MISUSE, AND ADDICTION

Concerta has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Abuse and misuse of CNS stimulants, including Concerta, can result in overdose and death (see section "If you accidentally take a higher dose"), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

1. WHAT IS THE MEDICINE INTENDED FOR?

Concerta is intended for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children over the age of 6, adolescents and adults up to the age of 65.
Concerta can improve the attention and concentration, and reduce impulsiveness and hyperactivity in individuals with ADHD.
Concerta is supposed to be given as part of an ADHD treatment program that can

include consultation or other therapies.

Therapeutic group: Central nervous system stimulant.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if you or your child:

- is sensitive (allergic) to the active ingredient (methylphenidate hydrochloride) or to any of the additional ingredients contained in the medicine (see section 6 - "Further Information").
- has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are involuntary repeated movements or sounds.
- is currently taking or has taken within the 14 days before starting Concerta treatment an antidepressant from the monoamine oxidase inhibitor (MAOI) group.
- Do not use Concerta in children under the age of 6 as the medicine has not been studied in this age group.

Special warnings regarding use of the medicine

Before beginning treatment with Concerta, tell the doctor if you or your child is suffering or has suffered from or has a family history of one of the following conditions:

- addiction/dependence or abuse of alcohol, prescription drugs or street drugs.
- heart problems, heart disease, heart defect, or high blood pressure.
- there is a family history of sudden death.
- mental problems, such as psychosis, mania, bipolar disorder or depression, or a family history of suicidality, bipolar disorder or depression.
- uncontrolled repetitive movements or sounds (tics) or Tourette's syndrome, or a family history of tics or Tourette's syndrome.
- seizures or abnormal brain scan (EEG) results.
- circulation problems in fingers and toes.
- intestinal problems – obstruction or narrowing of the intestine.
- eye problems, including increased intraocular pressure, glaucoma or far-sightedness.
- is pregnant or planning a pregnancy. It is not known if Concerta can harm the unborn baby.
- is breastfeeding or plans to breastfeed. It is not known if Concerta passes into breast milk. Consult the doctor about the best nutrition for the baby while taking Concerta.

The following problems were reported upon use of methylphenidate hydrochloride and other stimulants:

Abuse, misuse and addiction

Concerta has a high potential for abuse, which can lead to problems with administration of the medicine, including addiction. Abuse of Concerta, other medicines that contain methylphenidate and medicines that contain amphetamine, may lead to overdose and death. The risk of an overdose and death increases when

taking higher doses of Concerta or when taking them in a way that has not been approved, such as snorting or injection.

- Your doctor should check you or your child's risk for abuse, misuse and addiction before starting treatment with Concerta and will monitor your or your child's treatment.
- Concerta may lead to physical dependence after prolonged use, even if taken as directed by doctor.
- Do not give Concerta to anyone else. See section 1 "What is the medicine intended for?" for more information.
- Keep Concerta in a safe place and dispose of any remaining medicine. See section 5 "How should the medicine be stored?".
- Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Heart-related problems

- Sudden death in patients suffering from heart problems or a heart defect.
- Stroke and heart attacks in adults.
- Increased blood pressure and pulse.

In general, Concerta should not be used in children, adolescents or adults suffering from a heart defect or other serious heart problems.

Refer to a doctor immediately or proceed to the nearest hospital emergency room if you or your child develops symptoms of heart problems, such as chest pain, shortness of breath or fainting while using Concerta.

Increased blood pressure and heart rate

Stimulants may cause an increase in blood pressure and heart rate.

If you are taking medicines to treat high blood pressure and increased heart rate, your doctor will monitor blood pressure and heart rate parameters.

Mental (psychiatric) problems

- Stimulants may cause or worsen behavioral or thought problems in patients with an existing mental problem.
- Onset or worsening of bipolar disorder.
- New psychotic effects (e.g., hearing voices or seeing things that do not exist) or onset of new manic symptoms.

Tell your doctor about mental problems that your or your child suffers from, or of a family history of suicide, bipolar disease or depression.

Refer to a doctor immediately if you or your child experiences new onset or worsening of mental symptoms or problems while using Concerta, especially hearing voices and seeing things that are not real, believing in things that are not real or onset of new symptoms of mania.

Children and adolescents

Do not use Concerta in children under the age of 6, as the medicine has not been studied in this age group.

Tests and follow-up

Before commencing treatment with Concerta, the doctor will check you or your child for heart problems.

The doctor will regularly monitor your or your child's blood tests, blood pressure and heart rate during the course of treatment with Concerta.

The height and weight of children taking Concerta should be monitored frequently.

Concerta treatment may be stopped if a problem is found during these check-ups.

Drug interactions

If you or your child is taking, or has recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Concerta in combination with certain medicines may cause severe side effects. It is sometimes necessary to adjust the dosages of the medicines while taking Concerta. Your doctor will make a decision whether Concerta can be taken with other medicines.

In particular, inform the doctor or pharmacist if you or your child is taking any of the following:

- Monoamine oxidase inhibitors (MAOIs). Do not take Concerta if you or your child is currently taking or has taken within 14 days before starting treatment with Concerta, preparations for the treatment of depression from the MAOI group (also see Section 2 - subsection "Do not use the medicine...").
- Medicines to treat blood pressure.
- Vasoconstrictors (e.g., medicines for the treatment of colds or allergy that contain anticongestants).
- Anticoagulants from the coumarin group (e.g., warfarin).
- Medicines to treat seizures (e.g., phenobarbital, phenytoin, primidone)
- Medicines for the treatment of depression (e.g., tricyclic antidepressants and serotonin reuptake inhibitors).
- Medicine to treat a mental illness - risperidone.

Be familiar with the medicines that you or your child takes. Keep a list of your or your child's medicines to show the doctor and pharmacist the list of medicines that you or your child is taking, when receiving a new medicine.

Do not start taking new medicines during the course of treatment with Concerta without first talking to your doctor.

If you are due to undergo surgery

Inform your doctor if you are due to undergo surgery. This is because methylphenidate cannot be taken on the day of the surgery with a certain type of anesthetic. There is risk of increased blood pressure during surgery.

Use of the medicine and food

Swallow the tablet whole with water or another liquid.

The tablet can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant, breastfeeding or are planning to become pregnant, inform the doctor, who will decide if you can take Concerta.

Driving and operating machinery
Stimulating agents may impair your or your child's ability to operate dangerous machinery or to drive a vehicle.
Exercise caution, and only perform these activities if you or your child is sure that the medicine does not affect the ability to drive or to operate dangerous machinery.

Important information about some of the ingredients of the medicine
Concerta contains lactose. Consult the doctor before starting to use the medicine if you suffer from intolerance to certain sugars.
Sodium - This medicine contains less than 1 millimole (23 mg) sodium per tablet, i.e., it is considered essentially "sodium-free".

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dosage.
Concerta is an extended-release tablet. It releases the medicine to the body throughout the day. Therefore, **do not chew, crush or halve the tablet.**
Swallow the tablet whole with water or another liquid.
Tell the doctor if you or your child cannot swallow the tablet whole. It may be necessary to prescribe a different medicine for you/your child.
The tablet can be taken with or without food.
Take the tablet once a day, in the morning.
The Concerta tablet does not completely dissolve in the body. After all the medicine has been released, you may sometimes notice an empty tablet in the stool; this is normal.
Your doctor may occasionally stop Concerta treatment in order to check the symptoms of ADHD.

If you accidentally take a higher dose, side effects may occur as a result of overdose:
Cardiovascular effects: heart rate changes and disturbances, hypertension or hypotension.
Central nervous system effects: agitation and increased involuntary movements, feeling of confusion, hallucinations (see, feeling and hearing things that are not real).
Serotonin syndrome, seizures, stroke and coma.
Life-threatening high fever and rhabdomyolysis.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the

package of the medicine with you.

If you forget to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.
Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine, consult the doctor before discontinuing use of the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Concerta may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
Concerta may cause serious side effects. Refer to a doctor immediately in the following situations:

- **Abuse, misuse and addiction** (see section 2 "Before using the medicine").
- **Signs of allergy**, such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.
- **Symptoms of heart problems**, such as chest pain, shortness of breath or fainting. The following side effects have been reported on use of methylphenidate or other stimulants: sudden death in patients suffering from heart problems or a heart defect, stroke and heart attacks in adults, increased blood pressure and pulse.
- **Increased blood pressure and heart rate.** Stimulants may cause an increase in blood pressure and heart rate. If you are taking medicines to treat high blood pressure and rapid heart rate, your doctor will monitor your blood pressure and heart rate parameters.
- **Mental (psychiatric) problems**. new onset or worsening of mental symptoms or mental problems during the course of treatment with Concerta. Especially, seeing and hearing things that are not real, believing things that are not real or suspicious. Behavioral or thinking problems, depression, bipolar disorder. (see section 2 "Before using the medicine").
- **Seizures.** If you or your child develops seizures, your doctor will instruct you to stop the treatment.
- **Prolonged and painful erections (priapism).** There have been cases of priapism that required surgery in patients treated with methylphenidate. **If you or your child develops priapism, refer for medical assistance immediately**.
- **Circulation problems in the fingers and toes** (peripheral vasculopathy, including Raynaud's phenomenon). The symptoms may include:
    - Numbness, cold or pain sensation in the fingers or toes.

- Change in the skin color of the fingers or toes from pale to blue and red.

  Refer to a doctor if you or your child is suffering from numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

  Refer to a doctor immediately if you or your child develops signs of unexplained sores in the fingers or toes during the course of treatment with Concerta.

- **Slowed growth (height and weight) in children.** Height and weight of children should be frequently checked during the course of treatment with Concerta. If your child is not growing or gaining weight as expected, there may be a need to discontinue treatment.
- **Blockage of the intestine may occur**. Since Concerta tablets do not change their shape in the intestine (digestive system), people with serious intestinal problems (serious narrowing of the intestine) should not take Concerta.
- **Eye problems (increased intraocular pressure and glaucoma).** If you or your child develops vision changes or pain, swelling or redness in the eyes, refer to a doctor immediately.
- **Changes in vision or blurred vision.**
- **Onset or worsening of tics or worsening of Tourette's syndrome.** Inform the doctor immediately if you or your child is suffering from onset or worsening of tics or worsening of Tourette's syndrome during the course of treatment with Concerta**.**

Additional side effects:

Very common side effects:

In children:

- upper abdominal pain

In adults:

- decreased appetite
- headache
- dry mouth
- nausea
- insomnia
- anxiety
- dizziness
- weight loss
- nervousness
- increased sweating

Common side effects observed in clinical trials:

In children and adolescents: upper abdominal pain, vomiting, fever, nasopharyngitis (inflammation of the mucosa of the nose and pharynx, with suppurating nasal discharge), dizziness, insomnia, cough, pain in the mouth and pharynx.

In adults: rapid pulse, palpitations, vertigo (spinning sensation), blurred vision, dry mouth, nausea, indigestion, vomiting, constipation, irritability, upper respiratory tract

infection, weight loss, reduced appetite, anorexia (eating disorder), muscle tension, headache, dizziness, tremor, paresthesia, sedation, tension headache, insomnia, anxiety, primary insomnia, depressed mood and depression, nervousness, restlessness, aggression, teeth grinding, decreased libido, emotional instability, feeling confused, tension, pain in the mouth and pharynx, excessive sweating.

Additional side effects that have been reported in clinical trials:

Low white blood cell count (leukopenia), dry eyes, impaired accommodation (visual focus), hot flushes, abdominal discomfort or pain, diarrhea, weakness, fatigue, feeling tense/nervous, feeling thirsty, sinusitis, increased level of the alanine aminotransferase enzyme, increase in heart rate and blood pressure, heart murmur, muscle spasms, lethargy, sleepiness, psychomotor hyperactivity, anger, excessive alertness, mood swings, frequent fluctuations in mood, panic attack, sleep disorder, tendency to cry, tics, impotence, shortness of breath, skin rash, macular rash, hypertension.

Additional side effects reported upon use of the preparation:

Pancytopenia (too low a number of all blood cells - red, white and platelets), decreased platelet count (thrombocytopenia), thrombocytopenic purpura (bleeding characteristic of a very low platelet count).

Angina pectoris, slow pulse, heart rhythm disturbances.

Double vision, increased intraocular pressure, dilated pupils, vision problems.

Chest pains, chest discomfort, decreased effect of the medicine or response to the medicine, high fever.

Liver cell damage, acute liver failure.

Hypersensitivity reaction (allergy), such as angioedema, anaphylactic reaction, swelling of the ear, blisters on the skin, peeling of the skin, hives (a skin disease), itching, skin irritation and/or skin infection, rash.

Increased blood level of the alkaline phosphatase enzyme, increased bilirubin level in the blood, increased liver enzyme level in the blood, abnormal white blood cell and platelet counts.

Joint pains, muscle pains, muscle spasms, rhabdomyolysis.

Seizure, dyskinesia (repeated involuntary movements), serotonin syndrome (when combined with certain other medicines), motor and verbal tics.

A feeling of disorientation, hallucinations (visual or auditory), mania, excessive talking, libido changes, prolonged and painful erection (priapism), hair loss in different parts of the body (alopecia), skin redness (erythema), constriction of the blood vessels in the tips of the fingers and toes, typically following exposure to cold (Raynaud's syndrome).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Store Concerta in a safe place, such as a locked office.
Do not use the medicine after the expiry date (Exp. date) that appears on the package. The expiry date refers to the last day of that month.
Store below 25°C. Close the bottle tightly.
Discard remaining Concerta tablets that are not in use or which have expired in accordance with the following cautionary measures: mix the tablets with an undesirable nontoxic substance, such as dirt, cat litter or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away in the household trash.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:
polyethylene oxide 200K, povidone K29-32, succinic acid, stearic acid, butylated hydroxytoluene (BHT), polyethylene oxide 7000K, sodium chloride, ferric oxide black, ferric oxide yellow, ferric oxide red (27 mg and 54 mg tablets only), cellulose acetate 398-10, poloxamer 188, hypromellose 2910, 3 cps, phosphoric acid.

Color coating:
lactose monohydrate, HPMC, titanium dioxide, triacetin, ferric oxide yellow (18 mg and 54 tablets only), stearic acid (18mg tablet only), black iron oxide (27 mg tablet only), ferric oxide red (54 mg tablet only).

Transparent coating:
HPMC, polyethylene glycol (macrogol 400), carnauba wax.

Ink for printing:
black iron oxide, isopropyl alcohol, propylene glycol, HPMC, purified water.

Each 18 mg tablet contains: 6.84 mg lactose monohydrate
Each 27 mg tablet contains: 5.20 mg lactose monohydrate
Each 36 mg tablet contains: 17.60 mg lactose monohydrate
Each 54 mg tablet contains: 8.00 mg lactose monohydrate

What the medicine looks like and the contents of the package:
Concerta 18 mg: a yellow, capsule-shaped tablet, with “alza 18” imprinted on it in black ink
Concerta 27 mg: a gray, capsule-shaped tablet, with “alza 27” imprinted on it in black ink
Concerta 36 mg: a white, capsule-shaped tablet, with “alza 36” imprinted on it in black ink
Concerta 54 mg: a brown-red, capsule-shaped tablet, with “alza 54” imprinted on it in black ink

Each package contains 30 tablets.

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.
Manufacturer: Janssen-Cilag Manufacturing, LLC, Gurabo, Puerto Rico, 00778, United States.

Revised in May 2024.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Concerta 18 mg - 126-85-30589
Concerta 27 mg - 134-47-31123
Concerta 36 mg - 126-86-30590
Concerta 54 mg - 126-87-30591
Based on the American leaflet from October 2023.

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