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

The medicine is dispensed with a doctor's prescription only

CONCERTA®,

Prolonged-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".

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.

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").
- is very anxious, mentally tense, or agitated (suffers from restlessness – agitation)
- has an eye problem called glaucoma (increased intraocular pressure)
- has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are involuntary repeated movements or sounds.
- is 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:
- heart function problems, heart defects, or high blood pressure.
- there is a family history of sudden death.
- mental problems, such as: psychosis, mania, bipolar disorder, or depression.
- a family history of suicidality.
- tics or Tourette's syndrome.
- seizures or abnormal brain scan (EEG) results.
- circulation problems in fingers and toes.
- intestinal problems – esophagus, stomach, or intestine (small or large).
- addiction/dependence or abuse of alcohol, prescription medicines or recreational drugs.

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

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 if you or your child develops symptoms of heart problems, such as chest pain, shortness of breath or fainting while using Concerta.

Mental (psychiatric) problems
In all patients: Onset or worsening of the following problems: behavioral or thought problems, bipolar disorder, aggressive or hostile behavior.
In children and adolescents: Onset of psychotic symptoms (e.g., hearing voices, believing in things that are not real or suspicious) or of manic symptoms.
Refer to a doctor immediately if you or your child experiences new onset or worsening of mental symptoms or problems while using Concerta, especially seeing and hearing things that are not real, believing in things that are not real or suspicious.

Prolonged and painful erections (priapism)
Occurrence of prolonged and painful erections has been reported with use of methylphenidate. If you or your child develops this effect, refer to the doctor immediately because of the potential for irreversible damage.

Circulation problems in the toes and fingers (peripheral vasculopathy, including Raynaud's phenomenon)
- The fingers or toes may feel cold and painful or numb.
- The fingers or toes may change their color from pale to blue, to red.

Inform the doctor if you notice numbness, pain, skin color change or sensitivity to temperature in the toes or fingers.
Refer to your doctor immediately if bruises appear on your or your child's toes or fingers while taking Concerta.

Dependence and addiction
Use of the medicine may lead to dependence or abuse. Store the medicine in a safe place to prevent abuse. Selling the medicine or passing it on to other people may harm them and is illegal.

Children and adolescents
Do not use Concerta in children under the age of 6, since 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 frequently monitored.
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, vitamins 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 for the treatment of depression, such as tricyclic antidepressants and serotonin reuptake inhibitors.
- Antiepileptics (such as: phenobarbital, phenytoin, primidone).
- Anticoagulants (such as: warfarin and others).
- Medicines to treat blood pressure.
- Vasoconstrictors.
- Medicines for the treatment of colds or allergies that contain anticongestants.

Be familiar with the medicines that you or your child takes. Show the doctor and pharmacist the list of medicines that you or your child is taking. Do not start taking new medicines during the course of treatment with Concerta without first talking to your doctor.

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 essentially considered "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 a prolonged-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 can not 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:
Vomiting, restlessness, increased involuntary movements, muscle spasms, seizures, feeling of confusion, hallucinations (seeing, feeling or hearing things that are not real), increased sweating, headache, high fever, heart rate changes and disturbances, hypertension, rhabdomyolysis, dilated pupils, dry mouth.
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 Tablets 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.
Refer to a doctor immediately upon onset of:
- 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: increased blood pressure and pulse, stroke and heart attack in adults, sudden death in patients suffering from heart problems or a heart defect.
- 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, restlessness – excessive muscle movement, aggressive or hostile behavior.
- Mental (psychiatric) problems in children and adolescents: onset of psychotic symptoms (such as hearing voices, believing in things that are not real or suspicious) or onset of mania symptoms.
- Prolonged and painful erections (priapism). An immediate examination by the doctor is necessary due to risk of irreversible damage.
- Numbness, pain, change in skin color or sensitivity to temperature or appearance of unexplained wounds on the toes and fingers. These may be circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).
- Concerta may cause slowed growth rate (height and weight) in children.
- Seizures, especially in patients with a history of seizures.
- Vision changes or blurred vision.
- Blockage of the esophagus, stomach, small or large intestine, in patients who are already suffering from narrowing of these organs.

Additional side effects:

Very common side effects:
- decreased appetite
- dry mouth
- insomnia
- dizziness
- abdominal pain
- increased sweating
- headache
- nausea
- anxiety
- weight loss
- nervousness.

Common side effects observed in clinical trials:
Vomiting, fever, nasopharyngitis (inflammation of the mucosa of the nose and pharynx, with suppurating nasal discharge), cough, pharyngeal pain, rapid pulse, palpitations, vertigo (spinning sensation), blurred vision, indigestion, constipation, upper respiratory tract infection, reduced appetite, anorexia (eating disorder), feeling of muscle tension, tremor, paresthesia, sedation, tension headache, depressed mood and depression, restlessness, aggression, decreased libido, feeling confused, teeth grinding, tension, emotional instability.

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, heart murmur, muscle spasms, lethargy, sleepiness, psychomotor hyperactivity, anger, excessive alertness, mood swings, frequent fluctuations in mood, panic attack, sleep disorder, tendency to cry, uncontrollable speech and body movements (Tourette – tics), impotence, shortness of breath, skin rash, macular rash, hypertension.

Additional side effects reported upon use:
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, 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), 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.
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.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:
Butylated hydroxytoluene, carnauba wax, cellulose acetate, hypromellose, phosphoric acid, poloxamer, polyethylene oxides, povidone, sodium chloride, stearic acid, succinic acid, ferric oxides, cellulose acetate, opadry yellow, opadry clear, opadry gray, opadry white, opadry red, opacode black.

Each Concerta 18 mg tablet also contains:
6.84 mg lactose monohydrate
Each Concerta 27 mg tablet also contains:
5.20 mg lactose monohydrate
Each Concerta 36 mg tablet also contains:
15.20 mg lactose monohydrate
Each Concerta 54 mg tablet also 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 or 100 tablets.
Not all package sizes may be marketed.

Registration Holder and Importer: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Revised in November 2020 according to MOH's guidelines.

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

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