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

The medicine is dispensed with a doctor's prescription only

Methylphenidate Sandoz® 18 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
18 mg methylphenidate hydrochloride

Methylphenidate Sandoz® 36 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
36 mg methylphenidate hydrochloride

Methylphenidate Sandoz® 27 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
27 mg methylphenidate hydrochloride

Methylphenidate Sandoz® 54 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
54 mg methylphenidate hydrochloride

Inactive and allergenic ingredients: see section 2 under "Important information about some of the ingredients of the medicine" and 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, consult your 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 to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Methylphenidate Sandoz PRT 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.
Methylphenidate Sandoz PRT can improve attention and concentration and reduce impulsiveness and hyperactivity in people with ADHD. Methylphenidate Sandoz PRT is supposed to be given as part of an ADHD treatment program that may include counseling or other therapies.

Therapeutic group:
Central nervous system stimulant.

2. BEFORE USING THE MEDICINE

Do not use Methylphenidate Sandoz PRT if you or your child:

- is sensitive (allergic) to the active ingredient (methylphenidate hydrochloride) or to any of the other ingredients in this medicine (see section 6 – "FURTHER INFORMATION").
- is very anxious, mentally tense, or agitated (suffers from restlessness).
- 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 in the last 14 days before starting Methylphenidate Sandoz PRT treatment an antidepressant from the monoamine oxidase inhibitor (MAOI) group.
- Do not use Methylphenidate Sandoz PRT in children under the age of 6 as the medicine has not been studied in this age group.

Special warnings regarding use of Methylphenidate Sandoz PRT
Before beginning treatment with Methylphenidate Sandoz PRT, tell the doctor if you or your child is suffering, has suffered from or has a family history of any 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 (blood flow) problems in fingers and toes.
- digestive system problems – esophagus, stomach, or intestine (small or large).
- addiction/dependence or abuse of alcohol, prescription medicines or illegal drugs.

The following problems were reported with 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, Methylphenidate Sandoz PRT should not be used in children, adolescents or adults suffering from a heart defect or other serious heart problems.
Consult a doctor immediately if you or your child develops symptoms of heart problems such as chest pain, shortness of breath or fainting while using Methylphenidate Sandoz PRT.

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 things that do not exist or suspiciousness) or onset of manic symptoms.
Consult a doctor immediately if you or your child experiences new onset or worsening of mental symptoms or problems while using Methylphenidate Sandoz PRT, especially seeing and hearing things that are not there, believing in things that do not exist or suspiciousness.

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, consult a doctor immediately because of the potential for irreversible damage.
Circulation (blood flow) problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon)

- The fingers or toes may feel cold and painful or numb.
- The fingers or toes may change color from pale to blue, to red.

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

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 Methylphenidate Sandoz PRT 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 Methylphenidate Sandoz PRT, 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 Methylphenidate Sandoz PRT.
The height and weight of children taking Methylphenidate Sandoz PRT should be monitored frequently.
Methylphenidate Sandoz PRT 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.
Methylphenidate Sandoz PRT in combination with certain medicines may cause severe side effects. It is sometimes necessary to adjust the dosages of these medicines while taking Methylphenidate Sandoz PRT. Your doctor will decide whether Methylphenidate Sandoz PRT 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 Methylphenidate Sandoz PRT if you or your child is currently taking or has taken in the last 14 days before starting treatment with Methylphenidate Sandoz PRT, monoamine oxidase inhibitors (MAOI) (see also Section 2 – under "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 Methylphenidate Sandoz PRT 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 or breastfeeding or if you are planning to become pregnant, inform the doctor, who will decide whether you can take Methylphenidate Sandoz PRT.

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 operate dangerous machinery.

Important information about some of the ingredients of the medicine
The tablets contain lactose which is a type of sugar. If you have been told by your doctor that you cannot digest certain sugars, consult your doctor before taking this medicine.
Methylphenidate Sandoz 18 mg PRT prolonged-release tablets - Each tablet contains 6.31 mg lactose (monohydrate).
Methylphenidate Sandoz 27 mg PRT prolonged-release tablets - Each tablet contains 8.17 mg lactose (monohydrate).
Methylphenidate Sandoz 36 mg PRT prolonged-release tablets - Each tablet contains 8.43 mg lactose (monohydrate).
Methylphenidate Sandoz 54 mg PRT prolonged-release tablets - Each tablet contains 6.76 mg lactose (monohydrate).

Sodium:
Methylphenidate Sandoz 18 mg PRT
This medicine contains 7.8 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.39% of the recommended maximum daily dietary intake of sodium for an adult.

Methylphenidate Sandoz 27 mg PRT
This medicine contains 11.7 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.59% of the recommended maximum daily dietary intake of sodium for an adult.

Methylphenidate Sandoz 36 mg PRT
This medicine contains 15.6 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.78% of the recommended maximum daily dietary intake of sodium for an adult.

Methylphenidate Sandoz 54 mg PRT
This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially "sodium-free".

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
Do not exceed the recommended dosage.
Methylphenidate Sandoz PRT is a prolonged-release tablet. It releases the medicine to the body throughout the day. Therefore, do not chew, crush, or split the tablet.
Swallow the tablet whole with water or another liquid. Tell the doctor if you or your child is unable to swallow the tablet whole. It may be necessary to prescribe you/your child with a different medicine.
The tablet can be taken with or without food.
Take the tablet once a day, in the morning.
The Methylphenidate Sandoz PRT 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 Methylphenidate Sandoz PRT treatment in order to check the symptoms of ADHD.

If you accidentally take a higher dose
If you have accidentally taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
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 forget to take the medicine
If you forget to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.
Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine
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 every 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, using Methylphenidate Sandoz PRT 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.

Consult a doctor immediately if you get:

- 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 with 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 Methylphenidate Sandoz PRT, especially, seeing and hearing things that are not real, believing things that are not real or are 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 are suspicious) or onset of manic 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 fingers and toes. These may be circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).
- Methylphenidate Sandoz PRT 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
- tingling (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 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 enzyme alanine aminotransferase
- 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)
- erectile dysfunction
- shortness of breath
- skin rash
- macular rash
- hypertension.

Additional side effects reported with use:

- pancytopenia (too low numbers 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 pain, chest discomfort, decreased effect of the medicine or decreased 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 enzyme alkaline phosphatase, increased bilirubin level in the blood, increased level of liver enzymes in the blood, abnormal white blood cell and platelet counts
- joint pain, muscle pain, 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 any side effect worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. 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.
Storage conditions:
Do no store this medicine above 25°C.
Shelf-life after first opening - 6 months at a temperature not higher than 25°C.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:
Drug layer: polyethylene oxide, povidone (K25), succinic acid, stearic acid, butylhydroxytoluene.
Push layer: polyethylene oxide, sodium chloride, povidone (K25), stearic acid, iron oxide red (E172), butylhydroxytoluene.
Membrane layer: cellulose acetate, poloxamer 188.
Drug coat: hypromellose, succinic acid.
Film coat: film coating mixture (lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000.

Methylphenidate Sandoz 18 mg PRT tablets also contain:
iron oxide yellow (E172).

Methylphenidate Sandoz 27 mg PRT tablets also contain:
iron oxide black (E 172)

Methylphenidate Sandoz 54 mg PRT tablets also contain:
iron oxide red (E172), iron oxide yellow (E172).

What the medicine looks like and the contents of the package
Methylphenidate Sandoz 18 mg PRT: round, pale yellow, prolonged-release tablets, with a small hole on one side.
Methylphenidate Sandoz 27 mg PRT: round, pale gray, prolonged-release tablets, with a small hole on one side.
Methylphenidate Sandoz 36 mg PRT: round, white, prolonged-release tablets, with a small hole on one side.
Methylphenidate Sandoz 54 mg PRT: round, red, prolonged-release tablets, with a small hole on one side.

Each package contains 30 or 100 prolonged-release tablets.
Not all package sizes may be marketed.

Registration holder and importer's name and address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in April 2023 according to MOH's guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Methylphenidate Sandoz 18 mg PRT prolonged-release tablets: 169-42-36067-00
Methylphenidate Sandoz 27 mg PRT prolonged-release tablets: 169-43-36078-00
Methylphenidate Sandoz 36 mg PRT prolonged-release tablets: 169-44-36079-00
Methylphenidate Sandoz 54 mg PRT prolonged-release tablets: 169-45-36080-00