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® 27 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
27 mg methylphenidate hydrochloride

Methylphenidate Sandoz® 36 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
36 mg methylphenidate hydrochloride

Methylphenidate Sandoz® 54 mg PRT

Prolonged-release tablets

Composition:
Each tablet contains:
54 mg methylphenidate hydrochloride

Inactive and allergenic ingredients in this medicine: 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.

WARNING: ABUSE, MISUSE, AND ADDICTION
Methylphenidate Sandoz PRT has a high potential for abuse and misuse, which can lead to the development of substance use disorder, including addiction. Abuse and misuse of central nervous system stimulants, including Methylphenidate Sandoz PRT, can result in overdose and death (see section "If you have accidentally taken 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?

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").
- 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 an antidepressant from the monoamine oxidase inhibitor (MAOI) group in the last 14 days before starting Methylphenidate Sandoz PRT treatment.
- 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:
- addiction/dependence or abuse of alcohol, prescription medicines 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.
- involuntary repeated 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 (blood flow) problems in fingers and toes.
- intestinal problems – obstruction or narrowing.
- eye problems, including increased intraocular pressure, glaucoma or problems seeing up close (far-sightedness).
- is pregnant or planning a pregnancy. It is not known if Methylphenidate Sandoz PRT can harm the unborn baby.
- is breastfeeding or plans to breastfeed. It is not known if Methylphenidate Sandoz PRT passes into breast milk. Consult the doctor about the best nutrition for the baby while taking Methylphenidate Sandoz PRT.

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

Abuse, misuse, and addiction
Methylphenidate Sandoz PRT has a high potential for abuse, which can lead to problems with administration of the medicine, including addiction. Abuse of Methylphenidate Sandoz PRT, 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 Methylphenidate Sandoz PRT 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 Methylphenidate Sandoz PRT and will monitor your or your child's treatment.
- Methylphenidate Sandoz PRT may lead to physical dependence after prolonged use, even if taken as directed by the doctor.
- Do not give Methylphenidate Sandoz PRT to anyone else. See section 1 "What is the medicine intended for?" for more information.
- Keep Methylphenidate Sandoz PRT 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, Methylphenidate Sandoz PRT 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 Methylphenidate Sandoz PRT.

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 behavior disturbance or thought disorder 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 from which you or your child suffer/suffers, or of a family history of suicide, bipolar disease or depression.
Refer to a doctor immediately if you or your child experience/experiences new onset or worsening of mental symptoms or problems while using Methylphenidate Sandoz PRT, especially hearing voices and seeing things that are not real, believing in things that are not real or onset of symptoms of mania.

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 starting 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 the 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 Methylphenidate Sandoz PRT").
- Medicines to treat blood pressure.
- Vasoconstrictors (e.g., medicines for the treatment of colds or allergy that contain decongestants).
- 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).
- A 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 Methylphenidate Sandoz PRT 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 a 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 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.

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 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 for some time in order to check the symptoms of ADHD.

If you have accidentally taken 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 (seeing, feeling and hearing things that are not real). Serotonin syndrome, seizures, stroke and coma.
- Life-threatening high fever and rhabdomyolysis.

If you have 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 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
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.
Methylphenidate Sandoz PRT 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 with 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 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 (see section 2 "Before using the medicine").
- **Seizures.** If you or your child develops seizures, the 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 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 treatment with Methylphenidate Sandoz PRT.
- **Slowed growth (height and weight) in children.** Height and weight of children should be frequently checked during treatment with Methylphenidate Sandoz PRT. 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 Methylphenidate Sandoz PRT tablets do not change their shape in the intestine (digestive system), people with serious intestinal problems (serious narrowing of the intestine) should not take Methylphenidate Sandoz PRT.
- **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 treatment with Methylphenidate Sandoz PRT.

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, tingling (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 cell count (leukopenia)
- dry eyes
- impaired accommodation (visual focus)
- hot flashes
- abdominal discomfort or pain
- diarrhea
- weakness
- fatigue
- feeling tense/nervous
- feeling thirsty
- sinusitis
- increased level of the enzyme alanine aminotransferase
- increase in heart rate
- increase in 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 with 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, increased intraocular pressure, 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), 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 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.
Store Methylphenidate Sandoz PRT in a safe place such as a locked closet.
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 above 25°C.
Shelf-life after opening - 6 months at a temperature not higher than 25°C.
Discard remaining Methylphenidate Sandoz PRT 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:
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 (E172)

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.

License Holder and Importer's name and address:
Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel.

Revised in June 2024.

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