

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

The medicine is dispensed with a doctor's prescription only

Solian 100 mg, Tablets

Solian 400 mg, Film-coated Tablets

The active ingredient and its quantity:

Solian 100 mg: each tablet contains

Amisulpride 100 mg

Solian 400 mg: each film-coated tablet contains

Amisulpride 400 mg

Inactive ingredients: See section 6.

Read the leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need to read it again.

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?

The medicine is intended to treat schizophrenia.

Therapeutic group: Solian belongs to the substituted benzamide group of antipsychotics.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You have breast cancer or a prolactin-dependent tumor.
- You have a tumor on the adrenal gland (called pheochromocytoma).
- You are taking levodopa, a medicine for treatment of Parkinson's disease, and dopaminergic agonists such as bromocriptine, ropinirole (see section "Drug interactions").
- You have been diagnosed with a tumor in the pituitary gland.
- The patient is under 18 years of age.

Do not take the medicine if any of the above conditions applies to you. If you are not sure, consult with your doctor or pharmacist before taking Solian.

Special warnings regarding use of the medicine

❗ Before treatment with Solian, tell the doctor if:

- You have kidney problems.
- You have Parkinson's disease.
- You have ever had seizures (epileptic fits).
- You have an irregular heart rate.
- You have heart disease or you have a family history of heart problems.
- Your doctor has told you that you might have had a stroke.
- You or someone else in your family has a history of blood clots, since a correlation has been found between medicines such as Solian and formation of blood clots.
- You are diabetic or have been told you have an increased risk of having diabetes.

- You have a slow heartbeat (less than 55 beats per minute).
- You have been told that your blood potassium levels are low.
- You are elderly, as there is a greater chance of developing low blood pressure or feeling sleepy in the elderly. A small increase in the number of cases of death of elderly people with dementia has been reported for patients taking antipsychotics, compared to those not taking antipsychotics.
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual.

- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leukopenia – reduced number of white blood cells.
- You or someone else in your family has a history of breast cancer.
- You have high levels of prolactin.

Severe liver problems have been reported with Solian. Refer to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or you notice yellow discoloration of the eyes or skin.

If you are not sure if any of the conditions above apply to you, consult with your doctor or pharmacist before taking Solian.

❗ Children and adolescents

The medicine is not intended for children and adolescents under the age of 18, as the efficacy and safety of use of the preparation at these ages have not been proven.

❗ Tests and follow-up

Taking Solian may affect the results of some blood tests; these include tests to measure the hormone called prolactin and liver tests. If you are about to undergo blood tests, it is important to tell your doctor you are taking Solian.

❗ Drug interactions

If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Solian can affect the way some other medicines work. Likewise, some medicines can affect the way Solian works.

In particular, do not take Solian and tell the doctor if you are taking any of the following medicines:

- Levodopa – a medicine to treat Parkinson's disease.
- Medicines of the “dopaminergic agonist” group, such as ropinirole and bromocriptine.
- Consult the doctor if you are taking any of the following medicines:**
- Medicines used to control your heart rate, such as quinidine, disopyramide, amiodarone and sotalol.
- Clozapine, used to treat schizophrenia.
- Additional antipsychotic medicines used to treat mental problems.
- Medicines to treat severe pain called opiates, such as morphine or pethidine.
- Medicines to treat hypertension and heart problems, such as diltiazem, verapamil, guanfacine and digitalis.
- Clonidine, used to treat migraines, hot flushes or high blood pressure.
- Mefloquine to treat malaria.
- Medicines which help you sleep, such as barbiturates and benzodiazepines.

- Pain-killers, such as tramadol and indomethacin.
- Anesthetics.
- Antihistamines such as promethazine, which may cause sleepiness.

If you are not sure if any of the conditions above apply to you, consult with your doctor or pharmacist before taking Solian.

❗ Use of the medicine and food

Swallow the medicine with plenty of water before a meal.

❗ Use of the medicine and alcohol consumption

Do not drink alcohol during the course of treatment with the medicine. This is because alcohol may harm the way the medicine works.

❗ Pregnancy, breast-feeding and fertility

Consult the doctor before taking the medicine if you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant.

Pregnancy

Solian Tablets are not recommended during pregnancy and in women of child-bearing age not using proper contraception. If you use Solian Tablets during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, uncontrollable trembling of the body, sleepiness, breathing problems, or difficulty in feeding. Consult with your doctor if your baby develops any of these symptoms.

Breast-feeding

You should not breast-feed during treatment with Solian Tablets. Talk to your doctor about the best way to feed your baby if you are taking Solian Tablets.

❗ Driving and operating machinery

You may feel less alert, drowsy or sleepy and have blurred vision while taking the medicine. If this happens, do not drive or use any tools or machines.

❗ Important information about some of the ingredients of the medicine

This medicine contains lactose, a type of sugar.

If you have been told by your doctor that you can not tolerate certain sugars, consult with him before taking the medicine.

Solian contains sodium. This medicine contains less than 1 mmol sodium per tablet, that is to say, it is considered to be 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

How much to take

The dose of Solian that you take will depend on your illness. Be sure to follow the doctor's instructions exactly.

Adults

In general, if the daily dose is up to 400 mg, take the medicine once a day. If the daily dose is greater than 400 mg, the daily dose should be divided into twice daily.

Elderly

Your doctor will need to monitor your condition carefully as you are at greater risk for low blood pressure or sleepiness due to taking this medicine.

People with kidney problems

Your doctor may need to give you a lower dosage.

Children

Do not use this medicine in children and adolescents under 18 years of age.

Do not exceed the recommended dose.

Taking the medicine

- Take the medicine by mouth.
- The tablet can be halved. There is no information regarding crushing or pulverizing the tablet. Do not chew! Swallow the medicine with water.
- Take the medicine before a meal.
- If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but consult the doctor.

If you accidentally take a higher dosage

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, so that the doctor knows what you have taken. The following effects may occur: feeling restless or shaky, rigid muscles, feeling drowsy or sleepy, which could lead to a loss of consciousness.

If you forgot to take the medicine

If you forgot to take a dose of the medicine, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Keep taking Solian until the doctor tells you to stop. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If you stop, your illness may return or get worse. Do not stop taking Solian suddenly, unless you received an explicit instruction from your doctor. Suddenly stopping use may cause withdrawal effects, such as:

- Nausea or vomiting.
- Sweating.
- Sleeping difficulties or feeling restless.
- Muscle stiffness or unusual body movements.
- Symptoms of your illness may return.

Do not take medicines in the dark! Check the label and the dose each time you take a 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 Solian may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop use and refer immediately to a doctor or hospital if: Uncommon side effects (effects that may affect up to 1 in 100 users):

- You have an allergic reaction. The signs may include: an itchy, lumpy rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You experienced a seizure (epileptic fit).
- You get infections more frequently than usual. This can happen because of a blood disorder called agranulocytosis or a decrease in the number of white blood cells (leukopenia or neutropenia).

Rare side effects (effects that may affect up to 1 in 1000 users):

- You have a high temperature, sweating, stiff muscles, rapid heartbeat, rapid breathing and a feeling of confusion, drowsiness or agitation. These could be symptoms of a serious but rare side effect called neuroleptic malignant syndrome.

- You have a very rapid or unusual heart rate or chest pain, which could result in a heart attack or life-threatening heart disorder.

- You have blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs and cause chest pain and breathing difficulties. If you notice any of these symptoms, seek medical help immediately.

Refer to the doctor as soon as possible if you suffer from any of the following effects:

Very common side effects (may affect more than 1 in 10 users):

- Tremor, muscle stiffness or spasm, slow movement, secretion of more saliva than usual or feeling restless.
- Common side effects (may affect up to 1 in 10 users):
- Involuntary movements, mainly of the arms and legs (these symptoms can be reduced if the doctor reduces the dose of Solian or prescribes additional medication for you).

Uncommon side effects (may affect up to 1 in 100 users):

- Involuntary movements, mainly of the face or tongue.
- Additional side effects include:**
- Sleeping difficulties (insomnia) or feeling anxious or agitated.
- Feeling drowsy or sleepy.
- Constipation, nausea or vomiting, dry mouth.
- Weight gain.
- Unusual production of breast milk in men and women, breast pain.

- Menstrual period stops.
- Breast enlargement in men.
- Difficulty in getting or maintaining an erection, or in ejaculating.
- Feeling dizzy (can be due to low blood pressure).
- Blurred vision.

- Uncommon side effects (may affect up to 1 in 100 users):
- Slowing of the heart rate.
- High blood sugar (hyperglycemia).
- Feeling confused.
- Nasal congestion.
- A condition called “osteoporosis”. This is when your bones are more fragile.
- High levels of fats (triglycerides) or cholesterol in the blood.
- Accidental inhalation of food with risk of pneumonia (lung infection).
- Increase in blood pressure.
- Difficulty urinating.
- Liver tissue damage.

Rare side effects (may affect up to 1 in 1000 users):

- Benign tumor (such as prolactinoma).
- Malaise, confusion or weakness, nausea, loss of appetite, feeling nervous. This may be as a result of a disease called Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH).
- Tiredness, weakness, confusion, painful muscles, muscles that are still or do not work well. This may be due to low sodium levels in your blood.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Restless legs syndrome (uncomfortable feeling in legs temporarily relieved by movement and whose symptoms worsen at the end of the day).

- Increased sensitivity of your skin to sun and ultraviolet light.

- Falls due to reduced body balance, sometimes leading to fractures.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the 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, should be kept in a safe place out of the reach and sight of children and/or infants in order 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. Do not use Solian if you notice that the tablets are discolored. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

Storage conditions:

Do not store at a temperature above 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following ingredients:

Solian 100 mg

Lactose Monohydrate, Microcrystalline Cellulose, Sodium Starch Glycolate (type A), Hypromellose, Magnesium Stearate. Each tablet contains 69.6 mg lactose monohydrate.

Solian 400 mg

Lactose Monohydrate, Microcrystalline Cellulose, Sodium Starch Glycolate (type A), Hypromellose, Magnesium Stearate, Titanium Dioxide (E 171), Polyoxyl 40 Stearate. Each film-coated tablet contains 130.25 mg lactose monohydrate.

What the medicine looks like and the contents of the package:

Solian 100 mg: Round, flat, white to off-white tablets. “AMI 100” is engraved on one side and a score line is on the other side.

Solian 400 mg: Oblong, film-coated, white tablets, with a score line and engraved with “AMI 400”.

Pack sizes:

Each package contains 30 tablets.

Name of License Holder and Importer and its Address: sanofi-aventis Israel Ltd., P.O.B. 8090, Netanya.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

Revised in November 2021 according to MOH guidelines. Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Solian 100 mg: 1242530202

Solian 400 mg: 1242430203