PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

SOLIAN® 50 mg tablets

SOLIAN® 200 mg tablets

Amisulpride

Contains sugar:

SOLIAN 50 mg: Each tablet contains 34,80 mg lactose monohydrate.

SOLIAN 200 mg: Each tablet contains 139,20 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking SOLIAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SOLIAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SOLIAN is and what it is used for
2. What you need to know before you take SOLIAN
3. How to take SOLIAN
4. Possible side effects
5. How to store SOLIAN
6. Contents of the pack and other information.

1. What SOLIAN is and what it is used for

SOLIAN contains a medicine called amisulpride. This belongs to a group of medicines called antipsychotics. It is used to treat a mental illness called schizophrenia.

Schizophrenia can make you feel, see or hear things which do not exist, have strange and frightening thought(s), be suspicious or aggressive for no apparent reason, and make you feel alone.

Sometimes people with these symptoms may also feel tense, anxious or depressed. SOLIAN works by improving disturbed thoughts, feelings and behaviours. It is used to treat schizophrenia when it starts and also over the long-term.

2. What you need to know before you take SOLIAN

Do not take SOLIAN if:

- you are allergic (hypersensitive) to amisulpride or to any of the other ingredients of SOLIAN (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are pregnant, likely to become pregnant or are breastfeeding (see Pregnancy and breastfeeding).
- you have a prolactin-dependent tumour (tumour of the pituitary gland) or breast cancer.
- you have phaeochromocytoma (a tumour of the adrenal gland).
- you have kidney problems.
- you are a child under 18 years of age.
- you are taking medicines to control your heartbeat such as quinidine, disopyramide, amiodarone, sotalol.
- you have a congenital heart problem (QT-interval prolongation).
- you are taking other medicines that may affect your heartbeat such as bepridil, cisapride, sultopride, thioridazine, methadone, erythromycin injection, vincamine injection, halofantrine, pentamidine or sparfloxacin.
- you are taking levodopa (used to treat Parkinson’s disease).

Warnings and precautions:

Tell your doctor or healthcare provider before taking SOLIAN:

- if you are diabetic or have been told you have an increased risk of having diabetes. (Your glucose levels must be monitored carefully during treatment).
- if you have been told that you have an intolerance to some sugars, especially lactose. Contact your doctor before taking SOLIAN (see SOLIAN contains lactose).
- if you have kidney problems.
- if you have ever had fits (epileptic seizures).
- if you have Parkinson's disease. SOLIAN may worsen your symptoms.
- if you have heart disease or family history of heart problems.
- if you have an unusual heart rate (rhythm).
- if you have a slow heartbeat (less than 55 beats per minute).
- if you have been told you have a low amount of potassium in your blood.
- if you had a stroke previously or your doctor has told you that you might have a stroke.
- if you are elderly. This is because elderly people would be more likely to get low blood pressure or feel sleepy. An increase in the number of deaths of elderly people with dementia has been reported for patients taking antipsychotics compared to those not receiving antipsychotics.
- if you or someone else in your family has a history of blood clots, as medicines like SOLIAN have been associated with formation of blood clots.
- if you or someone else in your family has a history of breast cancer.
- if you have high levels of prolactin.
- if you have a low number of white blood cells in your blood (agranulocytosis). This means you may get infections more easily than usual.
- if you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia'.

Take special care with SOLIAN:

- Contact your doctor or pharmacist immediately and stop taking SOLIAN if you experience any of the following:
  - Higher than normal body temperature (hyperthermia).
  - Muscle stiffness.
  - Muscle pain in your shoulders, thighs or lower back, muscle weakness or trouble moving arms and legs, dark red or brown urine or increased urination (symptoms of rhabdomyolysis).
  - Elevated levels of creatinine phosphokinase (CPK) (blood test indicating muscle damage).
  - Dizziness upon standing, exercise intolerance, abnormal sweating, loss of appetite, bloating, diarrhoea, constipation, difficulty swallowing, trouble urinating including incomplete emptying of the bladder, ejaculation difficulties, difficult maintaining erections, blurry vision (symptoms of autonomic instability).
  - Changes in your level of consciousness.

  These are all symptoms of neuroleptic malignant syndrome (NMS) which is potentially life threatening (see section 4).
- Some side effects of SOLIAN may affect your ability to move and balance (see section 4). This could cause you to fall, sometimes leading to fractures.

Other medicines and SOLIAN:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

This is because SOLIAN can affect the way some other medicines work. Also, some medicines can affect the way SOLIAN works.

Tell your doctor if you are taking any of the following medicines:

- Medicines used to control your heartbeat such as quinidine, disopyramide, amiodarone and

sotalol.

- Bepridil (used to treat chest pain).
- Cisapride (used to treat heart burn).
- Medicines used to treat certain infections, such as erythromycin (by injection), pentamidine and sparfloxacin.
- Vincamine (by injection) (used for the prevention and treatment of dementia).
- Halofantrine (used to treat malaria).
- Medicines called ‘dopamine agonists’ such as levodopa, a medicine to treat Parkinson’s disease.
- Medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine and digoxin.
- Medicines which can cause low potassium levels including diuretics ("water tablets"), some laxatives, amphotericin B (by injection), glucocorticoids (used for conditions such as asthma or rheumatoid arthritis), tetracosactide (a diagnostic medicine used in the screening of patients presumed to have adrenocortical insufficiency).
- Other antipsychotic medicines used for mental problems, such as sultopride, thioridazine, pimozide, haloperidol.
- Antidepressant medicines, such as imipramine and lithium.
- Medicines for severe pain (narcotics), such as methadone.
- Pain killers (analgesics).
- Anaesthetics.
- Antihistamines which make you sleepy.
- Medicines which help you sleep, such as barbiturates and benzodiazepines.
- Clonidine used for migraines, flushing or high blood pressure.
- Clozapine used to treat schizophrenia.

SOLIAN with food, drink and alcohol

Do not drink alcohol while you are taking SOLIAN. This is because it can affect the way SOLIAN

works. SOLIAN also increases the effects of alcohol when taken together.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking SOLIAN.

Safety in pregnancy has not been established. If you use SOLIAN during pregnancy, your newborn baby may be adversely affected.

You should not breastfeed during therapy with SOLIAN tablets.

Driving and using machines

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

SOLIAN contains lactose

SOLIAN contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact to your doctor before taking SOLIAN.

3. How to take SOLIAN

Do not share medicines prescribed for you with any other person.

Always take SOLIAN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is between 50 mg (one tablet of SOLIAN 50 mg) and 800 mg (four tablets of SOLIAN 200 mg) per day.

The amount of SOLIAN you take will depend on your illness. Follow your doctor's instructions carefully.

Your doctor may start you on a lower dose, if necessary.

If necessary, your doctor can prescribe up to 1 200 mg each day which is the maximum daily dose.

Doses up to 400 mg each day can be taken as a single dose.

Doses above 400 mg should be taken as half in the morning and half in the evening.

Swallow the tablets whole with plenty of water. Do not chew your tablets.

Take SOLIAN before a meal and at about the same time(s) each day.

Do not stop taking SOLIAN just because you feel better. It is important to keep taking the tablets until your doctor tells you to stop.

If you have the impression that the effect of SOLIAN is too strong or too weak, tell your doctor or pharmacist. Do not change the dose yourself.

If you take more SOLIAN than you should:

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre.

Take the medicine pack with you, so that the doctor knows what you have taken.

The following effects may happen: feeling restless or shaky, rigid muscles, feeling drowsy or sleepy which could lead to a loss of consciousness.

If you forget to take SOLIAN:

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking SOLIAN:

Keep taking SOLIAN until your doctor tells you to stop. Do not stop taking SOLIAN just because you feel better. If you stop, your illness may get worse or come back.

4. Possible side effects

SOLIAN can have side effects.

Not all side effects reported for SOLIAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOLIAN, please consult your health care provider for advice.

If any of the following happens, stop taking SOLIAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 have a fit (seizure).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SOLIAN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- You get more infections than usual. This could be because of a blood disorder (agranulocytosis) or a decrease in the number of white blood cells (leucopenia or neutropenia).

- You have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be the symptoms of a serious side effect called neuroleptic malignant syndrome.
- Muscle pain in your shoulders, thighs or lower back, muscle weakness or trouble moving arms and legs, dark red or brown urine or increased urination. These could be symptoms of rhabdomyolysis (breakdown of muscles often leading to kidney damage).
- Elevated levels of CPK (blood test indicating muscle damage).
- You have a fast 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 causing chest pain and difficulty in breathing.
- You have trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless.
- You have movements that you cannot control, mainly of your head, neck, jaw or eyes.
- You have movements that you cannot control, mainly of your face or tongue.
- Aspiration pneumonia (a type of lung infection that occurs when food, saliva, liquids or vomit is breathed into the lungs or airways leading to your lungs, instead of being swallowed into your oesophagus and stomach.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Difficulty sleeping (insomnia) or feeling anxious or agitated.
- Trouble achieving an orgasm.
- Feeling drowsy or sleepy.
- Constipation, feeling or being sick, dry mouth.
- Putting on weight.

- Unusual production of breast milk in women and men, breast pain.
- Menstrual period stops.
- Breast enlargement in men.
- Difficulty in getting or maintaining an erection, or in ejaculating.
- Feeling dizzy (which can be due to low blood pressure).
- Blurred vision.

Less frequent side effects:

- Slowing of your heartbeat.
- High blood sugar (hyperglycaemia). Symptoms include passing large amounts of urine, excessive thirst and having dry skin.
- High levels of fat (triglycerides) or cholesterol in your blood.
- Increase in liver enzymes, which would be seen in a blood test.
- Feeling confused.
- Nasal congestion.
- A condition called osteoporosis, (when your bones are more likely to break) or osteopenia (bone weakening).
- Increase in blood pressure.
- Difficulty passing water (urine).
- Liver tissue damage, characterised by yellowing of your skin or eyeballs (jaundice) and pain in your stomach.
- Non-cancerous benign tumour (such as prolactinoma, characterised by irregular or no menstrual periods, milky discharge from your breasts when not pregnant or breastfeeding, vaginal dryness, acne and excessive body and facial hair growth).
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called a syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Low sodium levels in your blood. (Symptoms may include: feeling tired, weak, confused, have muscles that ache, are still or do not work well).

Frequency not known side effects:

- Falling, as a consequence of side effects compromising your body balance.
- Withdrawal symptoms seen in newborn babies where the mother has taken SOLIAN.
- Restless legs syndrome (uncomfortable feeling in legs temporarily relieved by movement and symptoms getting worse at the end of the day).
- Increased sensitivity of your skin to sun and ultraviolet light.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel.), or
- SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SOLIAN.

5. How to store SOLIAN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C (at normal room temperature), in a dry place.

Store in the original container.

Do not store in a bathroom.

Do not use after the expiry date shown on the blister and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLIAN contains:

SOLIAN 50 mg and SOLIAN 200 mg:

The active substance is amisulpride.

Each SOLIAN 50 mg tablet contains 50 mg of amisulpride.

Each SOLIAN 200 mg tablet contains 200 mg of amisulpride.

The other ingredients are: hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What SOLIAN looks like and contents of the pack:

SOLIAN 50 mg:

Round, white to off-white, flat-faced tablet, engraved AMI 50 on one face of the tablet.

SOLIAN 200 mg:

Round, white to off-white, flat-faced breakable tablet, engraved AMI 200 on one face and with a breakable bar on the other face of the tablet.

The tablets are available in PVC/aluminium blister packs of 10 tablets packed in cartons of 30 and 150 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

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