SOLIAN® Tablet

Amisulpride (100mg, 400mg)

What is in this leaflet

What Solian is used for

Solian contains a medicine called amisulpride.
This belongs to a group of medicines called 'antipsychotics'.
This medicine is used to treat people with schizophrenia. Schizophrenia is a mental illness characterized by various mental and behavioral disorders, such as hallucinations or agitation.

How Solian works

Solian works by improving disturbed thoughts, feelings and behaviour. It is used to treat schizophrenia when it starts and also over the long term.

Before you use Solian

-When you must not use it

Do not take Solian:

- if you are allergic to the active substance (amisulpride) or any of the other ingredients of this medicine. This is because this medicine may have an effect on your blood cells, i.e. reduce the number of white blood cells. This problem can be seen in a blood test,
- if you have a pheo*chromocytoma* (excessive growth of the adrenal glands around the kidneys, releasing substances which cause high blood pressure),
- in children under 15 years of age,
- if you have a prolactin-dependent tumor (prolactin is a hormone that stimulates milk production), e.g. breast cancer or pituitary disorders,
- if you are taking other medicines. If this is the case, make sure that combined use with Solian is not contraindicated.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Solian.

-Before you start to use it

Talk to your doctor or pharmacist before taking Solian.
Your doctor may ask you to have an electrocardiogram (ECG) before starting treatment. This medicine can cause heart rhythm disorders.
This medicine should be used with caution in the following situations:

- in elderly patients, particularly if they have dementia, because of the risk of a drop in blood pressure and of drowsiness; if the patients have kidney failure your doctor may reduce the dose,
- if you have risk factors for stroke, which occurs when the blood flow is abruptly interrupted in part of the brain,
- if you or a family member have a history of blood clots, since taking antipsychotic drugs may cause blood clots to form,
- if you have kidney disease (kidney failure), in which case your doctor may reduce the dose,
- if you have epilepsy or Parkinson's disease,
- if you have or at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Solian and regularly during treatment.
- if you have a history of hyperprolactinemia (too much prolactin in the blood) or a prolactin-dependent tumor (prolactin is a hormone that stimulates milk production), e.g. breast cancer or pituitary disorders. If this is the case, your doctor will have to monitor you closely during treatment.

Serious liver problems have been reported with Solian. Tell your doctor immediately if you experience tiredness, loss of appetite, nausea, vomiting, abdominal pain or yellowing of the eyes or skin.

During treatment, if you experience muscle rigidity or muscle loss associated with muscle pain (rhabdomyolysis), and if you have an increase in the level of the muscle enzyme creatine phosphokinase (CPK) in the blood and disturbances in consciousness accompanied by unexplained fever: stop your treatment immediately and consult your doctor urgently as this can have a potentially fatal outcome.

If you have visual disturbances or headaches during treatment, quickly talk to your doctor.

If you develop an infection or unexplained fever, your doctor may have you undergo a blood test immediately. This is because this medicine may have an effect on your blood cells, i.e. reduce the number of white blood cells. This problem can be seen in a blood test..

Treatment with this medicine should not be suddenly stopped because this can cause a withdrawal syndrome. This is characterized by signs such as insomnia, nausea and vomiting. Abnormal movements may also be observed and psychotic disorders recur.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

- Sedative agents that can have additive depressant effects on the central nervous system and contribute to a decrease in alertness: Morphine derivatives (analgesics, cough suppressants and replacement therapies), neuroleptics, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines (such as meprobamate), hypnotics, sedative

SOLIAN® Tablet

Amisulpride (100mg, 400mg)

antidepressants (amitriptyline, doxepin, mianserine, mirtazapine, trimipramine), sedative H1-antihistamines, centrally acting antihypertensives agents, baclofen and thalidomide.

- Drugs likely to induce torsades de pointes
  - Administered intravenously of dolasteron, erythromycin, spiramycin, and vincamine can cause arrhythmia. Using two torsadogenic drugs concomitantly is contraindicated.
  - citalopram, escitalopram, domperidone, hydroxyzine and piperaquine
- Contraindicated combinations
  - Non-antiparkinsonian dopamine agonists excluding antiparkinsonians (cabergoline, quinagolide)
  - Citalopram, escitalopram, domperidone, hydroxyzine, piperaquine, increase risk of ventricular arrhythmias, especially torsades de pointes
- Inadvisable combinations
  - Antiparasitics (chloroquine, halofantrine, lumefantrine, pentamidine)
  - Antiparkinsonian dopamine agonist (amantadine, apomorphine, bromocriptine, entacapone, lisuride, pergolide, piribedil, pramipexole, rasagiline, ropinirole, selegiline)
  - Class IA antiarrhythmics (quinidine,hydroquinidine, disopyramide) and class III antiarrhythmics (amiodarone, dronedarone, sotalol, dofetilide, ibutilide), and other drugs such as arsenic compounds, diphemanil, dolasetron IV, erythromycin IV, levofloxacin, mequitazine, mizolastine, prucalopride, vincamine IV, moxifloxacin, spiramycin IV, toremifene, vandetanib.
  - Other neuroleptics (chlorpromazine, cyamemazine, droperidol, flupenthixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sertindole, sulpiride, sultopride, tiapride, zuclopenthixol).
  - Alcohol consumption, levodopa, methadone, sodium oxybate, hydrochloroquine
- Combinations requiring precautions for use
  - Anagrelide, Azithromycin, ciprofloxacin, clarithromycin, levofloxacin, norfloxacin, roxithromycin
  - Beta-blockers in patients with heart failure (bisoprolol, carvedilol, metoprolol, nebivolol)
  - Bradycardia agents (particularly class IA antiarrhythmics, beta-blockers, certain class III antiarrhythmics, certain calcium channel blockers, digitalis glycosides, pilocarpine, anticholinesterase agents)
  - Potassium-depleting agents (potassium-lowering diuretics, alone or in combination, stimulant laxatives, glucocorticoids, tetracosactides and amphotericin B IV).
  - Lithium, ondansentron
- Combinations to be taken into consideration
  - Other sedative drugs, orlistat

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Solian is not recommended during pregnancy and in women of childbearing potential who are not using effective contraception.

If you use Solian during the last 3 months of your pregnancy, your baby may experience agitation, increased muscle stiffness, involuntary trembling, drowsiness, breathing problems or difficulty feeding or suckling.

If your baby has any of these symptoms, contact your doctor quickly.

Breast-feeding

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

Important information about some of the ingredients of Solian: This medicine contains a type of sugar (lactose) that is broken down into galactose and glucose. You should not use this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose/galactose malabsorption syndrome (rare hereditary diseases).

If your doctor has told you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

How to use Solian

Always take Solian exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not stop the treatment of your own accord.

This medicine should be taken by mouth.

Swallow the tablet(s) with a small amount of water.

-How much to use

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

Adults

• The usual dose is between 50mg and 800mg each day

• Your doctor may start you on a lower dose if necessary

• If necessary your doctor can prescribe up to 1200mg each day

• Doses up to 400mg each day can be taken as a single dose. Take the dose at the same time each day

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

Elderly

• Your doctor will need to keep a close check on you as you are more likely to have low blood pressure or sleepiness due to this medicine

SOLIAN® Tablet

Amisulpride (100mg, 400mg)

People with kidney problems
• Your doctor may need to give you a lower dose

Children and adolescents
- This medicine should not be given to children under 15 years of age.
- Use of this medicine is not recommended in children between 15 and 18 years of age.

-When to use it
• Take this medicine by mouth
• Swallow the tablets whole with a drink of water. Do not chew your tablets
• If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

-How long to use it
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. Unless your doctor tells you otherwise, Solian should not be stopped suddenly.
Stopping treatment suddenly may cause withdrawal effects such as:
• Difficulty sleeping or feeling very restless
• Muscle stiffness or unusual body movements
• Your original condition may come back

-If you forget to use it
If you forget to take Solian:
Do not take a double dose to make up for a forgotten dose. Take the following dose at the usual time.
If you have forgotten several doses, ask your doctor for advice.

-If you use too much (overdose)
If you take more tablets than you should:
You may experience drowsiness, sedation (a relaxing effect), a drop in blood pressure, extrapyramidal symptoms (particularly trembling and muscle stiffness) or you may fall into a coma.
If any of these occur, it is absolutely essential that you or your family/friends call a doctor or the emergency medical services.

While you are using it
-Things you must do
• Tell all the doctors, dentists and pharmacists who are treating you that you are taking Solian.
• If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Solian.
• 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 going to have a blood test, it is important to tell your doctor you are taking Solian.
• If you have any further questions on the use of this product, ask your doctor or pharmacist.

-Things you must not do
• Do not take more than the recommended dose unless your doctor tells you to. This can increase the risk of side effects.
• Do not give this medicine to anyone else, even if they have the same condition as yours.
• Do not use this medicine to treat any other complaints unless your doctor tells you to.
• Do not drink alcohol before or after taking this medicine. This can increase the risk of side effects.

-Things to be careful of
Driving and using machines
This medicine can cause drowsiness and blurred vision. You must take care if you drive a vehicle or use machines.
Side Effect
Like all medicines, Solian can cause side effects, although not everybody gets them.
If, during treatment, you develop muscle stiffness and consciousness disorders, along with an unexplained fever, stop treatment immediately and seek urgent medical attention.

The following side effects are very common (affecting more than 1 patient in 10):
- trembling, muscle stiffness, cramps, abnormal movements, producing more saliva than usual.

The following side effects are common (affecting 1 to 10 patients in 100):
- stiff neck, oculogyric crises (abnormal movement of certain eye muscles), intense contraction of jaws,
- somnolence,
- insomnia, anxiety, agitation,
- constipation, nausea, vomiting, dry mouth.
- frigidity (lack of sexual pleasure in women),
- hyperprolactinemia (too much prolactin, the hormone that induces milk production, in the blood), which may cause:

  o in women: absence of menstrual periods, abnormal production of breast milk, breast pain,

  o in men: swelling of breasts, impotence (erection difficulties).
- weight gain,
- low blood pressure (hypotension),
- blurred vision,

The following side effects are uncommon (affecting 1 to 10 patients in 1 000):
- involuntary movements of the tongue and/or face
- seizures (involuntary contractions of one or more muscles)
- hyperglycaemia (too much sugar in the blood)
- hypertriglyceridemia (too much fat (triglycerides) in the blood)
- hypercholesterolaemia (too much cholesterol in the blood)

SOLIAN® Tablet

Amisulpride (100mg, 400mg)

- slow heartbeat
- increased levels of certain liver enzymes, mainly transaminases
- liver tissue injury
- reduced bone density or change in bone structure (osteopenia, osteoporosis), weakening the bones
- allergic reactions
- confusion
- stuffy nose
- lung disorders (aspiration pneumonia) that may appear as inflammation, difficulty breathing, an infection, cough (mainly in combination with other drugs with a central nervous depressant effect),
- increase in blood pressure
- difficulty urinating
- leukopenia, neutropenia (see section 2, paragraph "Warnings and precautions").

The following side effects are rare (affecting 1 to 10 patients in 10 000):

- agranulocytosis (a low level of white blood cells) (see section 2, "Warnings and precautions")
- benign pituitary tumour, which may cause signs such as visual disturbances or headaches
- drop in the amount of sodium in the blood (hyponatremia), syndrome of inappropriate antidiuretic hormone secretion
- unexplained fever, along with general and neurological disorders
- serious fainting (loss of consciousness), heart rhythm disorders possibly causing death (see section 2)
- swelling, pain and redness of the legs. This is because blood clots in the veins (particularly in the legs) can move through blood vessels to reach the lungs, causing chest pain and difficulty breathing
- sudden swelling of the face and/or neck that can lead to difficulty breathing and may be life- threatening (angioedema), red, itchy patches on the skin (hives).

The following side effects may occur, but their frequency is not known:

- withdrawal syndrome in newborn infants.
- restless legs syndrome (uncomfortable feeling in the legs that is temporarily relieved by movement, and is worse at the end of the day).

  increased skin sensitivity when exposed to sun and ultraviolet rays.
- increased skin sensitivity when exposed to sun and ultraviolet rays
- falls due to loss of balance, which may involve fractures.
- destruction of muscle fibres and muscle pain (rhabdomyolysis),
- increased levels of creatine phosphokinase in the blood (blood test indicating muscle injuries).

Talk to your doctor or pharmacist if you experience:

- Increases in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during sleep (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

Tell your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the npra.gov.my
[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Solian
If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage
-Keep this medicine in a safe place where children cannot see or reach it.
-Do not use Solian after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
-Do not use Solian if you notice that the tablets become discoloured.
-Store below 30°C, away from heat and humidity.

Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
What it looks like
• Solian 100mg are white to off-white scored tablets, engraved "AMI 100". They are supplied in blister packs of 30.
• Solian 400mg tablets are white, scored film-coated tablets engraved "AMI 400". They are supplied in blister packs of 30.

Ingredients:
• The tablets contain 100mg or 400mg of the active substance, amisulpride.
• The inactive ingredients in Solian 100mg tablets are sodium starch glycolate, lactose monohydrate,

microcrystalline cellulose, hypromellose and magnesium stearate.
• The inactive ingredients in Solian 400mg tablets are sodium starch glycolate, lactose monohydrate, microcrystalline cellulose, hypromellose, magnesium stearate, polyoxyl 40 stearate and titanium dioxide.

MAL Numbers:
Solian Tablet 100mg:
MAL20032239ACZ
Solian Tablet 400mg:
MAL20032240ACZ

Manufacturer and Product Registration Holder
Manufacturer

Delpharm Dijon6, Boulevard De L'Europe,
21800 Quetigny, France.

Product Registration Holder
Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1,
Level 18-1, Tower B, Plaza 33
No.1 Jalan Kemajuan,
Seksyen 13,
46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision
26/06/2024

Serial Number: NPRA (R1/3)
14062024/118