

PACKAGE LEAFLET: INFORMATION FOR THE USER

Solian® 100 mg scored tablets

amisulpride

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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 belongs to a group of medicines known as 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLIAN

Contraindications:

Do not take Solian:

- if you are allergic to the active ingredient, amisulpride, or any of the other ingredients of Solian. See section 6 for a full list of ingredients.
- if you have a pheochromocytoma (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 are breast-feeding,
- 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 another medicine which should not be taken when you are already taking Solian (see "Taking or using other medicines").

If you are unsure of anything, do not hesitate to ask your doctor or pharmacist for advice.

Appropriate precautions for use ; special warnings:

Warnings and precautions for use

Your doctor may ask you to have an electrocardiogram (ECG) before starting treatment. This medicine can cause heart rhythm disorders (see section 4, "Possible side effects").

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; in the case of patients with kidney failure, your doctor may reduce the dose,
- if you have risk factors for stroke, which occurs when the bloodflow 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 diabetes or if you have risk factors for diabetes.
- 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.

If, during treatment, you develop muscle stiffness and consciousness disorders, along with an unexplained fever, stop treatment immediately and contact your doctor straightaway.

If you develop an infection or unexplained fever, your doctor may need to check your blood 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 (see Section 4, "Possible side effects").

Children:

- 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.

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/using other medicines

You must not take this medicine with cabergoline, quinagolide (medicines used to treat milk production disorders), citalopram or escitalopram (medicines used to treat anxiety or depression), domperidone (medicine used to treat nausea and vomiting), hydroxyzine (medicine used to treat anxiety or hives).

You must avoid taking

this medicine with:

- some medicines used to treat Parkinson's disease (amantadine, apomorphine, bromocriptine, entacapone, lisuride, pergolide, pramipexole, pramipexole, rasagiline, ropinirole, rotigotine, selegiline, tolcapone),
- levodopa,
- sodium oxybate (medicine used to treat narcolepsy),
- some medicines which may cause serious heart rhythm disorders (torsades de pointes) such as:
 - medicines used to treat irregular heart beat (class Ia antiarrhythmics such as quinidine, hydroquinidine, disopyramide and class III antiarrhythmics such as amiodarone, dronedarone, sotalol, dofetilide and ibutilide),
 - some medicines used to treat psychiatric disorders (chlorpromazine, cyamemazine, droperidol, flupenthixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sulpiride, sultopride, tiapride, zuclophenthixol),
 - some antiparasitic agents (chloroquine, halofantrine, lumefantrine, pentamidine),
 - a medicine used to treat dependence on some drugs (methadone),
 - other medicines such as: arsenic compounds, diphenamil, dolasetron IV, erythromycin IV, levofloxacin, mequitazine, mizolastine, prucalopride, vincamine IV, moxifloxacin, spiramycin IV, toremifene, vandetanib,
- medicines containing alcohol.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Solian with food and drink

As with all antipsychotic drugs in this group, you must avoid drinking alcoholic beverages during treatment.

Pregnancy

Use of this medicine is not recommended during pregnancy.

If you discover that you are pregnant, consult your doctor immediately. Only your doctor can decide whether it is necessary to continue treatment.

If you took Solian during the last 3 months of pregnancy, your baby may have the following symptoms: trembling, muscle stiffness and/or weakness, drowsiness, agitation, breathing problems, feeding problems.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

You must not breast-feed if you are taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine can cause drowsiness. You must take care if you drive a vehicle or use machines.

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.

3. HOW TO TAKE SOLIAN

Dosage

Always take the dose prescribed by your doctor. If you are unsure of anything, ask your doctor or pharmacist.

Do not stop the treatment of your own accord.

Method of administration

This medicine should be taken by mouth. Swallow the tablet(s) with a drink of water.

If you take more Solian 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, you or your family/friends must call a doctor or the emergency medical services.

If you forget to take Solian:

Do not take a double dose. Take the following dose at the usual time.

If you have forgotten several doses, ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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, hypersalivation.

► 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,
- drowsiness,
- 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:
 - in women: absence of menstrual periods, abnormal production of breast milk, breast pain,
 - in men: swelling of breasts, impotence (erection difficulties).
- weight gain,
- low blood pressure (hypotension),

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

- involuntary movements of the tongue and/or face,
- convulsions (involuntary contractions of one or more muscles),
- hyperglycemia (too much sugar in the blood),
- slow heart beat,
- increased levels of certain liver enzymes, mainly transaminases,
- allergic reactions.

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

- unexplained fever, along with general and neurological disorders,
- hypertriglyceridemia (too much fat (triglycerides) in the blood),
- hypercholesterolemia (too much cholesterol in the blood),
- confusion,
- serious fainting (loss of consciousness), heart rhythm disorders possibly causing death (see "What you need to know before you take Solian"),
- 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),
- leukopenia, neutropenia, agranulocytosis (a low level of white blood cells) (see the "Special warnings" section under "What you need to know before you take Solian"),
- withdrawal syndrome in newborn infants (see the "Pregnancy" section under "What you need to know before you take Solian").

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLIAN

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the box.

The expiry date refers to the last day of that month.

Do not store above 25° C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Solian 100 mg scored tablets contain

The active substance is:

Amisulpride.....100 mg
for one scored tablet.

The other ingredients are:

Sodium starch glycolate (Type A), lactose monohydrate, microcrystalline cellulose, hypromellose, magnesium stearate.

What Solian looks like and contents of the pack

This medicine is a scored tablet.

Each box contains 15, 30, 100 or 150 scored tablets.

Not all pack sizes may be marketed in your country.

Conditions of prescription and issue

List I

Marketing Authorization Holder and Operating Company

sanofi-aventis France
82, avenue Raspail
94250 Gentilly - France

Manufacturer

Delpharm Dijon
6, boulevard de l'Europe
21800 Quétigny - France

This leaflet was last approved in September 2015.