Package leaflet: Information for the user

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Solian® 50mg 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, ask your doctor or pharmacist.
* 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 'anti-psychotics'. It is used to treat an illness called schizophrenia.

Schizophrenia can make you feel, see or hear things which do not exist, have strange and frightening thoughts, change how you act, 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 behaviour. 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 this medicine and tell your doctor if:
* You are allergic (hypersensitive) to amisulpride or 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, might become pregnant or are breast-feeding (see 'Pregnancy and breast-feeding' section)
* You have breast cancer or something called 'a prolactin dependent tumour'
* You have a pituitary tumour
* You have a tumour on the adrenal gland (called phaeochromocytoma)
* You are taking other medicines which could change your heart rate such as medicines which are used to control your heart beat (see 'Taking other medicines' section)
* You are taking levodopa, a medicine to treat Parkinson's disease (see 'Taking other medicines' section)
* The patient is under 15 years old

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.

Warnings and precuations
Take special care with Solian
Check with your doctor or pharmacist before taking your medicine if:
* You have kidney problems
* You have Parkinson's disease
* You have ever had fits (epileptic seizures)
* You have a history or a family history of breast cancer
* You have high levels of prolactin, a hormone produced in the pituitary gland
* You have an unusual heart rate (rhythm)
* You have heart disease or family history of heart problems
* Your doctor has told you that you might have a stroke
* You are diabetic or have been told you have an increased risk of having diabetes
* You are elderly. This is because elderly people would be more likely to get low blood pressure or feel sleepy
* You are elderly and have dementia
* Your doctor has told you that you have an increased risk of a blood clot
* You have a slow heart beat (less than 55 beats per minute)
* You have been told you have a low amount of potassium in your blood.

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

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Solian can affect the way some other medicines work. Also some medicines can affect the way Solian works.

In particular, do not take this medicine, and tell your doctor if you are taking any of the following medicines:
* Medicines used to control your heart beat such as quinidine, disopyramide, procainamide, amiodarone and sotalol
* Bepridil, used to treat heart disease
* Cisapride, used to treat heartburn
* Thioridazine or sultopride, used to treat mental illness
* Methadone, used to treat pain and opiate addiction
* Antibiotics such as erythromycin (given by injection) or sparfloxacin
* Vincamine (given by injection), used for brain circulation problems
* Halofantrine, used for malaria
* Pentamidine used for pneumonia
* Levodopa, a medicine to treat parkinson's disease
* Clozapine, used to treat schizophrenia

Tell your doctor if you are taking any of the following medicines:
* Medicines for depression or to calm emotional and mental illness such as pimozide, haloperidol, imipramine, and lithium
* Medicines for severe pain called opiates such as morphine or pethidine
* Medicines for high blood pressure and migraine such as clonidine, diltiazem and verapamil, guanfacine and digitalis
* Medicines which may lower potassium levels. This includes water tablets such as bendrofluazide or hydrochlorothiazide, some laxatives, glucocorticoids (used to treat severe asthma and other inflammatory disorders), tetracosactides and amphotericin (used to treat fungal infections)
* Medicines which help you sleep such as barbiturates and benzodiazepines
* Pain-killers such as tramadol and indometacin
* Anaesthetics
* Antihistamines such as promethazine which make you sleepy

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

Taking Solian with food and drink
* Swallow Solian tablets with plenty of water before a meal
* Do not drink alcohol while you are taking Solian. This is because it can affect the way the medicine works

Pregnancy and breast-feeding
Do not take this medicine if:
* You are breast-feeding or planning to breast-feed

The following symptoms may occur in newborn babies, of mothers that have used Solian in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant.

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

Important information about some of the ingredients of Solian
Solian contains lactose, a type of sugar. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking this medicinal product.

3 How to take Solian

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

Taking this medicine
* Take this medicine by mouth
* Swallow the tablets whole with a drink of water. Do not chew your tablets
* Take before a meal
* 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 much to take
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
* 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

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(amisulpride)

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

Children under 15 years of age
Solian Tablets should not be given to children under 15 years of age

If you take more Solian than you should
If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so 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 a forgotten dose. 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:
* Feeling or being sick
* Sweating
* Difficulty sleeping or feeling very restless
* Muscle stiffness or unusual body movements
* Your original condition may come back

Blood Tests
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.

4 Possible side effects

Like all medicines, Solian can cause side effects, although not everybody gets them.
Stop taking Solian and see a doctor or go to a hospital straight away if:
* 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 but rare side effect called ‘neuroleptic malignant syndrome', which is a potentially fatal complication.
* You have an unusual heart rate, very fast heart rate or chest pain which could result in a heart attack or life-threatening heart disorder
* You have pain or swelling in your leg, chest pain or difficulty breathing. These could be symptoms of a blood clot

Uncommon (may affect up to 1 in 100 people):
* You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
* You have a fit (seizure)

Rare (may affect up to 1 in 1000 people):
* 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 (neutropenia)
* You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'

Tell your doctor as soon as possible if you have any of the following side effects:
Very common (may affect more than 1 in 10 people):
* Trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless.

Common (may affect up to 1 in 10 people):
* Movements that you cannot control, mainly of the arms and legs (These symptoms can be reduced if your doctor lowers your dose of Solian or prescribes an additional medicine)

Uncommon (may affect up to 1 in 100 people):
* Movements that you cannot control, mainly of the face or tongue

Other side effects include:
Common (may affect up to 1 in 10 people):
* Difficulty sleeping (insomnia) or feeling anxious or agitated
* 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)

Uncommon (may affect up to 1 in 100 people):
* Slowing of the heart beat
* High blood sugar (hyperglycaemia)
* Increase in blood pressure
* Difficulty in passing water (urine)
* Confusion
* Nasal congestion
* Problems with your liver
* Osteopaenia (low bone mineral density)
* Osteoporosis. This is when your bones are more likely to break
* You develop a lung infection after inhaling food, liquid, saliva or nasal secretions (aspiration pneumonia)
* Blood disorders such as Hypertriglyceridemia (high levels of triglycerides in your blood) and Hypercholesterolemia (high levels of cholesterol in your blood)

Rare (may affect up to 1 in 1000 people):
* Urticaria (hives)
* Swelling beneath the skin (angioedema)
* Hyponatraemia (low sodium levels in your blood)
* Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be signs of an illness called syndrome of inappropriate antidiuretic hormone secretion (SIADH)
* Benign (non-cancerous) pituitary tumour such as prolactinoma

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse.
This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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.
This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister foil.The expiry date refers to the last day of that month.
Do not use Solian if you notice that the tablets become discoloured.

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 contains
The active substance is amisulpride. Each tablet contains 50 mg amisulpride.

The other ingredients in Solian are:
Lactose monohydrate, Microcrystalline cellulose, Sodium starch glycolate Hypromellose and Magnesium stearate.

What Solian looks like and contents of the pack
Solian 50mg tablets are white to off-white, flat-faced tablets engraved AMI 50.
They are available in blister packs of 60.

The Parallel Product Authorisation Holder is:
LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:
Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:
Delpharm Dijon, 6 Boulevard de l’Europe, 21800 Quetigny, France.

Solian is a registered trademark of Sanofi.

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Is this leaflet hard to see or read?
Phone LTT Pharma Limited,
Tel: +44 (0)1527 505414
for help.