

# SOLIAN<sup>®</sup> SCORED TABLET

Amisulpride 100mg, 400mg

## What is in this leaflet

1. What Solian is used for
2. How Solian works
3. Before you use Solian
4. How to use Solian
5. While you are using it
6. Side effects
7. Storage and Disposal of Solian
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Solian is used for

Solian contains a medicine called amisulpride.

This belongs to a group of medicines called 'antipsychotics'.

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.

## 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 (hypersensitive) to amisulpride or any of the other ingredients of Solian.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × You are breast-feeding (see 'Pregnancy and breastfeeding' section)
- × You have breast cancer or something called 'a prolactin dependent tumour'
- × You have a tumour on the adrenal gland (called pheochromocytoma)

- × 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.

### Before you start to use it

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 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
  - ▲ If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
  - ▲ You are diabetic or have been told you have an increased risk of having diabetes
  - ▲ 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.
  - ▲ You are elderly. This is because elderly people would be more likely to get low blood pressure or feel sleepy.
- A small 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 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:

- Levodopa, a medicine to treat Parkinson's disease
- Medicines used to control your heart beat such as quinidine, disopyramide, amiodarone and sotalol
- Other anti-psychotic medicines used for mental problems
- Medicines for severe pain called opiates such as morphine or pethidine
- Medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine and digitalis
- Mefloquine used to treat malaria
- Medicines which help you sleep such as barbiturates and benzodiazepines
- Pain-killers such as tramadol and indomethacin
- 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.

### Pregnancy and breast-feeding

Do not take this medicine if:

- You are breast-feeding or planning to breastfeed

The following symptoms may occur in newborn babies, of mothers that have used Solian Tablets 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.

**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 cannot tolerate some sugars, talk to your doctor before taking this medicinal product.

**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.

- Swallow Solian tablets with plenty of water
- Do not drink alcohol while you are taking Solian. This is because it can affect the way the medicine works

**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

**People with kidney problems**

- Your doctor may need to give you a lower dose

**Children under 18 years of age**

- Solian should not be given to children under 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 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.**

**If you use too much (overdose)**

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.

**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**

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

**Side Effect**

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'
- 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 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. If you notice any of these symptoms seek medical advice immediately.

Tell your doctor as soon as possible if you have any of the following side effects:

**Very Common** (affects more than 1 in 10 people)

- Trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless.

**Common** (affects less than 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)
- 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** (affects less than 1 in 100 people)

- Movements that you cannot control, mainly of the face or tongue
- 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
- Fit (seizure)
- Slowing of the heart beat
- High blood sugar (hyperglycaemia)

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: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### **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.

#### **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:  
**MAL20032239A**  
Solian Tablet 400mg:  
**MAL20032240A**

### **Manufacturer and Product Registration Holder**

#### **Manufacturer**

Sanofi Winthrop Industrie  
6, Boulevard De L'Europe,  
21800 Quetigny, France.

#### **Product Registration Holder**

Sanofi-aventis (Malaysia) Sdn. Bhd.  
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### **Date of revision**

This leaflet was prepared on 27 June 2014 (based on CCDS V5-SmPC Mar11).