

# Solian 100mg/ml Solution

Amisulpride

SANOFI 



Is this leaflet hard to see or read?

Phone 0845 372 7101 for help

**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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## In this leaflet:

1. What Solian Solution is and what it is used for
2. Before you take Solian Solution
3. How to take Solian Solution
4. Possible side effects
5. How to store Solian Solution
6. Further information

### 1. What Solian Solution is and what it is used for



The name of your medicine is Solian 100mg/ml Solution (called Solian Solution throughout this leaflet). Solian Solution 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 Solution works by improving disturbed thoughts, feelings and behaviour. It is used to treat schizophrenia when it starts and also over the long term.

### 2. Before you take Solian Solution



**Do not take this medicine and tell your doctor if:**

- × You are allergic (hypersensitive) to amisulpride or any of the other ingredients of Solian Solution (listed in Section 6 below).  
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
  - × 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 used to treat Parkinson's disease (See 'Taking other medicines' section).
  - × You have been diagnosed with a pituitary tumour.
  - × The patient is under 18 years of age
- 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 Solution.



### Take special care with Solian Solution 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 are 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.
- ▲ You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual.
- ▲ You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'.
- ▲ You or someone else in your family has a history of breast cancer.
- ▲ You have high levels of prolactin.



Severe liver problems have been reported with Solian Solution.

Talk to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or yellow discoloration of the eyes or skin.

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



### **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 Solution can affect the way some other medicines work. Also some medicines can affect the way Solian Solution 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
- Drugs called 'dopamine agonists' such as ropinirole and bromocriptine

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

- Medicines used to control your heart beat such as quinidine, disopyramide, amiodarone and sotalol.
- Clozapine used to treat schizophrenia.
- Other anti-psychotic medicines used for mental problems.
- Medicines for severe pain called opiates such as morphine or pethidine.
- Mefloquine used to treat malaria.
- Medicines for high blood pressure and heart problems such as diltiazem, verapamil, guanfacine or digitalis.
- Clonidine used for migraines, flushing or high blood pressure.
- Medicines which help you sleep such as barbiturates and benzodiazepines.
- Pain-killers such as tramadol or 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 Solution.

### **Taking Solian Solution with food and drink**

- Take the solution with a drink that does not contain alcohol
- Do not drink alcohol while you are taking Solian Solution. This is because it can affect the way the medicine works

### **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 Solution is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

If you use Solian Solution during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, involuntary trembling of the body, sleepiness, breathing problems, or difficulty in feeding. Talk to your doctor, if your baby develops any of these symptoms.

#### Breast-feeding

You should not breast-feed during therapy with Solian Solution. Talk to your doctor about the best way to feed your baby if you are taking Solian Solution.



### **Driving and using machines**

You may feel less alert, drowsy or sleepy and have blurred vision 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 Solution**

Solian Solution contains small amounts of ethyl alcohol (ethanol), less than 100mg per ml.

Solian solution also contains parahydroxybenzoates (E216 propylhydroxybenzoate and E218 methylhydroxybenzoate), these may cause allergic reactions (these may be delayed).

### **3. How to take Solian Solution**

Always take Solian Solution 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.
- Take the solution with a drink that does not contain alcohol.
- Use the graduated syringe to measure your medicine. Each 1ml of solution contains 100mg of your medicine.
- 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 Solution you take will depend on your illness. Follow your doctor's instructions carefully

#### **Adults**

- The usual dose is between 50mg (0.5ml) and 800mg (8ml) each day.
- Your doctor may start you on a lower dose if necessary.

- If necessary your doctor can prescribe up to 1200mg (12ml) each day.
- Doses up to 300mg (3ml) each day can be taken as a single dose. Take the dose at the same time each day.
- Doses above 300mg (3ml) 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 Solution should not be given to children under 18 years of age

#### If you take more Solian Solution than you should

If you take more solution 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 Solution

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 stop taking Solian Solution

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



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 Solution can cause side effects, although not everybody gets them.

**Stop taking Solian Solution and see a doctor or go to a hospital straight away if:**

**Uncommon (may affect up to 1 in 100 people)**

- 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).
- 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 (leukopenia or neutropenia).

**Rare (may affect up to 1 in 1000 people)**

- 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 a very 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. 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 (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)
- Blurred vision

#### **Uncommon (may affect up to 1 in 100 people)**

- Slowing of the heart beat
- High blood sugar (hyperglycaemia)
- Feeling confused
- Nasal congestion
- A condition called 'osteoporosis'. This is when your bones are more likely to break
- High levels of fat (triglycerides) or cholesterol in the blood
- Accidental inhalation of food with risk of pneumonia (lung infection)
- Increase in blood pressure
- Difficulty passing water (urine)
- Liver tissue damage

#### **Rare (may affect up to 1 in 1000 people)**

- Noncancerous benign tumour (such as prolactinoma).
- 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).
- Tired, weak, confused, have muscles that ache, are still or do not work well. This may be due to low sodium levels in your blood

#### **Not known (frequency cannot be estimated from available data)**

- 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.

#### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Solian Solution**

Keep this medicine in a safe place where children cannot see or reach it.

Store below 25°C.

Do not use Solian Solution after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month. Solian Solution should be disposed of 2 months after opening.

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.

## **6. Further information**

### **What Solian 100mg/ml Solution contains**

- Each 1ml of solution contains 100mg of the active ingredient, amisulpride.
- The other ingredients are Saccharin sodium, sodium gluconate, glucono delta lactone, hydrochloric acid, methyl parahydroxybenzoate, propyl parahydroxybenzoate, potassium sorbate, caramel flavour (tonka beans extract, vanillin, benzaldehyde, acetyl methyl carbinol, gamma and delta decalactones, esters from acetic, butyric and 2 methyl butyric acid, esters from ethyl and cinnamyl alcohol, propylene glycol and ethyl alcohol) and purified water

### **What Solian Solution looks like and contents of the pack**

- Solian Solution is a clear yellow liquid, with an odour of caramel
- Solian Solution comes in a 60ml brown glass bottle, with a child resistant cap. It is provided with a 5ml oral syringe graduated in mg.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

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#### Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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