

SOLAVERT®

sotalol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SOLAVERT. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SOLAVERT against the benefits this medicine is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What SOLAVERT is used for

This medicine is used to treat “arrhythmias”, which is a problem when the heart beats too quickly or with the wrong rhythm.

SOLAVERT contains sotalol hydrochloride, which belongs to the family of drugs known as beta-blockers. It slows down and steadies the heart beat, reducing the effort the heart has to put into pumping blood.

Your doctor will have explained why you are being treated with this medicine and told you what dose to take.

SOLAVERT is only available with a doctor’s prescription.

There is no evidence that this medicine is addictive.

Before you take it

When you must not take it

Do not take SOLAVERT if you are allergic to sotalol hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- skin rash, itching or hives
- swelling of the face, lips, tongue or any parts of the body.

Do not take SOLAVERT if you have asthma.

You should not take this medicine if you have allergies, or problems with your kidneys or thyroid gland, unless you have discussed it with your doctor.

You should not take this medicine if you are pregnant or are breast feeding, or if you may become pregnant or intend to breast feed.

If you have any problems with your heart or circulation, discuss them with your doctor.

You should not take SOLAVERT with any other medicines or drugs which your doctor does not know about, particularly if they are to control high blood pressure, heart conditions, depression, hayfever, allergies, infections or diabetes.

You should contact your doctor if you have any diarrhoea or other illness while taking SOLAVERT.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

- **Make sure your doctor knows what other medicines you are already taking including ones you have bought yourself at the chemist or supermarket.**
- **In particular remind your doctor if you have asthma, bronchitis or any allergies such as hay fever, food allergies or are allergic to bee or wasp stings.**
- **Make sure your doctor is aware of any kind of heart disease, diabetes, phaeochromocytoma, kidney disease or thyroid disease that you have or have had, or if you have been told that your pulse is slow or irregular.**
- **Tell your doctor if you have ever had trouble with the levels of salts like potassium or magnesium in your blood.**
- **Remind your doctor if you are going to have surgery involving a general anaesthetic even if it is only minor.**
- **Tell your doctor if you are pregnant, if you are planning to become pregnant, or if you are breast feeding.**
- **Tell your doctor if you have been given SOLAVERT (or any other beta-blocker) before and if you had any problems.**
- **Remind your doctor if you have hardening of the arteries (cold fingers and toes or pain in the back of your legs when you walk).**

Be careful driving or operating machinery until you know how SOLAVERT affects you.

As with other medicines, it may cause dizziness, light-headedness or drowsiness in some people. If this occurs do not drive or operate machinery or undertake any other activity that could be dangerous if you are dizzy, light-headed or drowsy.

Taking other medicines

Some medicines can affect the way SOLAVERT works.

You should always tell your doctor about any other medicines you take, even those bought without a doctor's prescription.

It is especially important that you tell your doctor if you are taking any of the following:

- medicines which lower blood pressure (including other beta-blockers)
- any other medicine used to treat an irregular heart rhythm or beat
- digoxin, a medicine used for heart failure
- medicines used to treat angina or other heart conditions
- antidepressants (medicines used to treat depression)
- insulin or other drugs used to control diabetes
- medicines used to control or prevent asthma (inhalers or tablets) or to control allergies or which are used for other lung problems
- antihistamine medicines including terfenadine and astemizole that may be used to treat hayfever, allergies or to relieve symptoms of colds and flu
- quinolone antibiotics (medicines used to treat infections)
- diuretics (water tablets)
- some medicines used during surgery or emergency situations, such as anaesthetics.

If you are not sure whether you are taking any of these medicines,

check with your doctor or pharmacist.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide on the dose for you, and they may need to change the dose a few times to get the best level for you.

The usual dose is 80mg to 160mg twice a day. Your doctor may need to increase this as a very few patients may need up to three to four 160mg tablets spread over a day. The dosage may need to be different if you have a kidney problem.

How to take it

You should take your tablets with water one to two hours before meals. Do not take them with milk or meals.

How long to take it for

If you have been prescribed SOLAVERT tablets, you must be sure to follow your doctor's instructions very carefully.

Do not stop taking SOLAVERT tablets suddenly, the dose needs to be reduced gradually over 7 to 14 days.

If you forget to take it

It is important not to miss a dose but if you do, take your next dose at the normal time and with the normal amount.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SOLAVERT. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

Too much of this medicine will cause your blood pressure and heart rate to drop to dangerous levels. Serious heart problems may develop and this could be fatal.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SOLAVERT.

This medicine helps most people with arrhythmia, but it may have unwanted side effects in some people. Rarely, serious heart problems can develop while you are taking normal doses but you must remember that you are taking this medicine because your heart already has a serious problem. It is very important that your doctor keeps a check on your progress.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dizziness, lightheadedness or fainting, especially when you get up from a sitting or lying

position. Getting up slowly may help

- tiredness, lack of energy, weakness
- headache, fever
- irritated eyes, blurred vision, worsening of eyesight, increased sensitivity of the eyes to sunlight
- feeling sick, vomiting, stomach upset, diarrhoea, wind
- change in taste sensation
- anxiety, depression, mood changes
- problems with sexual function
- sleep problems, unusual dreams
- worsening of psoriasis
- hearing disturbances
- tingling or numbness in the hands or feet, cold limbs

Tell your doctor immediately or go to casualty at the nearest hospital if you notice any of the following:

- chest tightness, wheezing, shortness of breath
- very slow heart beat
- fast, irregular heart-beat, palpitations
- chest pain
- any type of skin rash, itching
- shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build up

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking SOLAVERT, even if it is not on this list.

While you are taking it

Things you must do

If you become pregnant while taking SOLAVERT, tell your doctor.

Your doctor can discuss with you the risks of taking it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SOLAVERT.

Tell any other doctor, dentist or pharmacist who treats you that you are taking this medicine.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not let yourself run out of tablets over weekends or on holidays.

After taking it

Storage

Store your tablets safely in a cool dry place. Protect from light and moisture.

Do not store them or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets in the original blister pack they are provided in until it is time to take them.

If you take the tablets out of the blister pack they will not keep well.

Keep all medicines out of the reach of children.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Product description

What it looks like

SOLAVERT 80mg tablets are light blue, biconvex, capsule shaped tablets, plain on one side and engraved 'S', '80' and a break bar on the other side.

SOLAVERT 160mg are light blue biconvex, capsule shaped tablets, plain on one side and engraved 'S', '160' and a break bar on the other side.

SOLAVERT 80 mg and 160 mg tablets are available in blister packs of 60.

Ingredients

SOLAVERT 80 mg tablets contain 80mg sotalol hydrochloride per tablet.

SOLAVERT 160 mg tablets contain 160mg sotalol hydrochloride per tablet.

The tablets also contain-

- microcrystalline cellulose
- magnesium stearate
- maize starch
- lactose (anhydrous)
- stearic acid
- colloidal anhydrous silica
- indigo carmine (CI 73015)

Supplier

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

SOLAVERT 80 mg blister – AUST R 79916

SOLAVERT 160 mg blister – 79918

This leaflet was revised in July 2016