

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM:

SOTAN 75 mg (tablets)

SOTAN 150 mg (tablets)

SOTAN 300 mg (tablets)

Read this entire leaflet carefully before you start taking SOTAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SOTAN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SOTAN CONTAINS:

The active substance is irbesartan.

SOTAN 75 mg: Each uncoated tablet contains 75 mg irbesartan.

SOTAN 150 mg: Each uncoated tablet contains 150 mg irbesartan.

SOTAN 300 mg: Each uncoated tablet contains 300 mg irbesartan.

The other ingredients are: calcium hydrogen phosphate dihydrate, hypromellose, microcrystalline cellulose, polysorbate 80, silica colloidal anhydrous, sodium starch glycolate, sodium stearyl fumarate, talc.

2. WHAT SOTAN IS USED FOR:

SOTAN is indicated for the treatment of essential high blood pressure. It may be used either alone or in combination with other high blood pressure medication.

SOTAN is also used for the treatment of certain cases of diabetic nephropathy in patients with Type 2 diabetes and hypertension.

3. BEFORE YOU TAKE SOTAN:

Do not take SOTAN:

- If you are allergic to any of the ingredients in **SOTAN** (see **WHAT SOTAN CONTAINS**).
- If you have experienced swelling of different areas of your body e.g. skin of your face, tongue or hands, when previously taking the ACE inhibitor class of antihypertensive medicines or medicines in the same class as **SOTAN** or if you suffer from this type of swelling with no known cause or if you have a family history of swelling/fluid retention. You should never take these medicines again.
- If you suffer from severe kidney disease.
- If you suffer from a narrowing of arteries to one or both of your kidneys.
- If you are taking lithium or antihypertensive medicines known as diuretics such as spironolactone, triamterene or amiloride.
- If you suffer from a thickening of your heart muscle or narrowing of your aorta.
- If you suffer from porphyria.
- If you are pregnant or breastfeeding your baby.
- If you suffer from high blood sugar or kidney function impairment and are taking any medicines which contain aliskerin which is also used to treat high blood pressure.
- **SOTAN** should not be given to children as the safety and effectiveness in children has not been established.

Take special care with SOTAN:

- **SOTAN** has been associated with low blood pressure in patients without other medical conditions.
- If you are taking diuretics or if you are on a salt restricted diet, or are on haemodialysis, you may suffer from sodium/volume depletion and consequent low blood pressure. Volume and/or sodium-depletion should be corrected before initiating therapy with **SOTAN**, or a lower starting dose should be considered.
- If you have other medical problems, especially severe congestive heart failure.

- If you suffer from several renal disease, excessive proteins in your urine and/or heart failure, it may cause you to have an excess of potassium in your body which can lead to death.
- If you are exercising or exposed to hot weather because of risk of dehydration, which may result in hypotension.
- If you experience severe nausea, vomiting, or diarrhoea while taking **SOTAN**, inform your doctor because of the risk of dehydration, which may result in low blood pressure.
- If you are on other blood pressure lowering medicines which fall into the class of angiotensin-receptor blockers, ACE-inhibitors or aliskiren containing medicines you may suffer from low blood pressure, increased levels of potassium in your blood and changes in your kidney function. Tell your doctor about any other blood pressure lowering medicines that you may be taking.

Taking SOTAN with food or drink:

SOTAN may be taken with or without meals preferably at the same time every day.

Pregnancy and Breast-feeding:

The safety of **SOTAN** in pregnant or breast-feeding mothers has not been established. If you are planning to become pregnant consult your doctor as you will need to be placed on alternative medication. Women of childbearing age should ensure effective contraception.

Should you become pregnant while taking **SOTAN**, the treatment must be stopped promptly and your doctor will switch you to a different class of antihypertensive medicine.

If you are pregnant or breast-feeding, please consult your doctor, pharmacist or other health care professional for advice before taking **SOTAN**.

Driving and using machinery:

SOTAN may cause side effects such as dizziness, headaches and nervousness which may impair concentration, therefore you should be careful until you know the effect that **SOTAN** has on you.

Taking other medicines with SOTAN:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Take special care when taking the following medicines with SOTAN:

- Non-steroidal anti-inflammatories (NSAIDs) such as aspirin as it may worsen your kidney disease, especially if you are dehydrated, and it may increase the blood pressure lowering effect of **SOTAN**.
- Lithium, as it may cause an increase in lithium concentrations in your blood resulting in lithium toxicity.
- Potassium supplements or antihypertensive medicines such as amiloride, triamterene or spironolactone which cause an increase in potassium in your body.
- Other blood pressure lowering medicines such as angiotensin-receptor blockers, ACE-inhibitors or aliskiren containing medicines as you may suffer from low blood pressure, increased levels of potassium in your blood and changes in your kidney function.

4. HOW TO TAKE SOTAN:

Always take **SOTAN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual recommended initial and maintenance dose is 150 mg once daily, with or without food.

If your blood pressure is not sufficiently controlled your doctor may increase your dose to 300 mg, or may add another antihypertensive medicine for you to take.

Your doctor will tell you how long your treatment with **SOTAN** will last. If you have the impression that the effect of **SOTAN** is too strong or too weak, tell your doctor or pharmacist.

If you take more SOTAN than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of SOTAN:

Do not double dose to make up for forgotten individual doses, as it will cause a dangerous lowering of your blood pressure.

5. POSSIBLE SIDE EFFECTS:

SOTAN can have side effects.

Not all side effects reported for **SOTAN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking SOTAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your face, hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing and swallowing.
- rash or itching,
- fainting,
- inflammation of blood vessels including inflammation of small veins, causing hard, purple blotches on the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SOTAN**. You may need urgent medical attention or hospitalisation.

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

- yellowing of the skin and eyes, also called jaundice,

- rapid lowering in blood pressure (symptoms of which may be lightheadedness or dizziness, particularly when standing up),
- liver problems (signs of which may be yellowing of the eyes and skin and flu like symptoms).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- A cough or cold symptoms
- Nausea, vomiting, diarrhoea, indigestion, change in your sense of taste.
- Sexual dysfunction
- Muscle pain and cramps
- Feeling of tiredness
- Ringing in your ears, dizziness, headache
- Anxiety or nervousness
- A rash

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF SOTAN:

Store in a dry place at or below 25 °C.

Keep HDPE containers tightly closed.

Keep the blisters in the carton until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF SOTAN:

SOTAN 75 mg / 150 mg / 300 mg :

Blister Pack:

Tablets are packed in Clear 250 micron PVC film coated with 60 GSM PVDC and Printed 25 micron silver-grey Aluminium foil. Each blister contains 10 Tablets.

Pack size: **30's** – Each carton contains 3 blisters of 10 Tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE container of 33 mm neck finish with a white 33 mm – 400 RS closure with induction sealing wad containing Cotton coil, 9 gm/yd.

Each container contains 30 Tablets. Each HDPE container is enclosed in an outer cardboard carton.

Pack size: **30's** - One HDPE container contains 30 Tablets.

8. IDENTIFICATION OF SOTAN:

SOTAN 75 mg:

White to off-white biconvex oval shaped uncoated tablets debossed with 'H 28' on one side and plain on other side.

SOTAN 150 mg:

White to off-white biconvex oval shaped uncoated tablets debossed with 'H 29' on one side and plain on other side.

SOTAN 300 mg:

White to off-white biconvex oval shaped uncoated tablets debossed with 'H 30' on one side and plain on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

SOTAN 75 mg: 45/7.1.3/1051

SOTAN 150 mg: 45/7.1.3/1052

SOTAN 300 mg: 45/7.1.3/1053

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

Aurogen South Africa (Pty) Ltd
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11. DATE OF PUBLICATION:

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