PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ISOPTIN SR 240 mg sustained release tablets

Verapamil hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking ISOPTIN SR 240 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- ISOPTIN SR 240 mg 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.

What is in this leaflet

1. What ISOPTIN SR 240 mg is and what it is used for
2. What you need to know before you take ISOPTIN SR 240 mg
3. How to take ISOPTIN SR 240 mg
4. Possible side effects
5. How to store ISOPTIN SR 240 mg
6. Contents of the pack and other information.

1. What ISOPTIN SR 240 mg is and what it is used for

ISOPTIN SR 240 mg contains verapamil hydrochloride and belongs to a group of medicines called calcium channel blockers.

ISOPTIN SR 240 mg is used to treat:

- Angina (severe pain in the chest arising from the heart).
- Mild to moderate high blood pressure.
- Increased and irregular heartbeat.

- Preventative treatment of irregular heartbeat relapse after electro-cardioversion.

2. What you need to know before you take ISOPTIN SR 240 mg

Do not use ISOPTIN SR 240 mg:

- If you are hypersensitive (allergic) to verapamil hydrochloride or any of the other ingredients of ISOPTIN SR 240 mg (listed in section 6).
- If your blood pressure is extremely low and is associated with cardiogenic shock (a condition where the heart cannot supply enough blood to your body, which causes symptoms such as difficulty in breathing, weakness and passing out).
- If you have recently had a heart attack with complications.
- If you do not wear a pacemaker, and you have been told by your doctor you have second or third degree heart block.
- If you have been told by tour doctor you have heart problems such as heart failure, sick sinus syndrome, an irregular heartbeat, or conditions called Wolff-Parkinson-White (WPW) or Lown-Ganong-Levine syndrome.
- If you are already taking medicine containing ivabradine for the treatment of certain heart conditions.
- If you are using beta-blockers to treat high blood pressure or heart conditions.

If you are unsure if any of the list applies to you, ask your doctor before you start to take your ISOPTIN SR 240 mg tablets.

If any of the above applies to you, please tell your doctor or pharmacist.

Warnings and precautions

Take special care with ISOPTIN SR 240 mg:

- If you experience mild cardiac conduction disorders between the atrium and ventricles (first degree AV block).
- If you have a heart disease that affects the heart muscle (hypertrophic cardiomyopathy).
- If you have low blood pressure.
- If you have liver or kidney problems.

- If you have neuromuscular disease (e.g. Myasthenia gravis, Lambert-Eaton syndrome, progressive Duchenne muscular dystrophy).

Other medicines and ISOPTIN SR 240 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Make sure you tell your doctor if you take:

- Medicines to control your blood pressure such as prazosin, terazosin.
- Diuretic medicines (sometimes called “water pills”).
- Medicines to regulate your heartbeat such as quinidine, flecainide, amiodarone, disopyramide.
- Medicines to treat angina pectoris or heart failure such as ivabradine.
- Medicines to control asthma such as theophylline.
- Medicines to control seizures such as carbamazepine, phenytoin.
- Medicines to control depression or anxiety such as lithium, phenobarbital, midazolam, buspirone or imipramine.
- Antidiabetic medicines such as glibenclamide.
- Medicines to control gout (e.g. sulfinpyrazone, colchicine).
- Medicines known as beta-blockers (e.g. propranolol or metoprolol).
- Medicines used for the induction and maintenance of general anaesthesia such as halothane.
- Digitalis medicines such as digoxin or digitoxin.
- Cimetidine to control stomach acid reflux.
- Medicines to suppress your immune system such as cyclosporine, everolimus, sirolimus or tacrolimus.
- A medicine called doxorubicin, used in cancer therapy.
- Medicines to control migraine headaches such as almotriptan.
- Certain medicines to lower your cholesterol levels (“statins” e.g. atorvastatin, lovastatin, simvastatin).
- Antibiotic medicines such as clarithromycin, erythromycin, telithromycin or rifampicin.

- Anti-fungal medicines such as clotrimazole, ketoconazole, itraconazole.
- The herbal medicine, St. John's wort.
- Medicines to treat AIDS or HIV such as ritonavir.
- Medicines to relax the muscles.
- Aspirin.
- Medicines that prevent blood clotting such as dabigatran and other direct oral anticoagulants.
- Grapefruit juice.
- Alcohol.

Tell your surgeon or dentist that you are taking ISOPTIN SR 240 mg if surgery is planned. It may affect the anaesthetic or other treatments used.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get new medicine. They can tell you if it is okay to take ISOPTIN SR 240 mg with other medicines.

ISOPTIN SR 240 mg with food, drink and alcohol

- Avoid alcohol while using ISOPTIN SR 240 mg. ISOPTIN SR 240 mg will increase the time it takes your body to get rid of alcohol. This means that you will not have to drink as much for your blood to be above the legal limit to drive. It will also take you longer to sober up.
- Avoid grapefruit juice while using ISOPTIN SR 240 mg. This may increase your risk of side effects from ISOPTIN SR 240 mg.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The effects of ISOPTIN SR 240 mg on your unborn baby are not known. Verapamil hydrochloride does cross the placenta and can be detected in umbilical vein blood at delivery.

ISOPTIN SR 240 mg can pass into your breast milk. You should not breastfeed while taking

ISOPTIN SR 240 mg.

Driving and using machines

It is not always possible to predict to what extent ISOPTIN SR 240 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ISOPTIN SR 240 mg affects you. ISOPTIN SR 240 mg increase the alcohol levels in your blood. Therefore, you will not have to drink as much for your blood alcohol level to be above the legal limit to drive.

ISOPTIN SR 240 mg contains sodium

- This medicine contains 34 mg sodium (main component of cooking/table salt) in each sustained release tablet. This is equivalent to 1,70 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take ISOPTIN SR 240 mg

Do not share medicines prescribed for you with any other person.

Always take ISOPTIN SR 240 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor may adjust your dose. Do not change your dose unless your doctor tells you to do so.

Usual dose of ISOPTIN 240 mg SR tablets:

Angina and increased or irregular heartbeat: Half to one tablet every 12 hours.

High blood pressure: One tablet per day (preferably in the morning).

If, after a week, your doctor is not happy with your body's response to ISOPTIN SR 240 mg, the doctor may increase the dose to one tablet in the morning, and half a tablet at night. You should never take more than one tablet every 12 hours.

- Swallow your tablets whole do not chew them. If it helps, you can wash them down with a glass of water. ISOPTIN SR 240 mg tablets should preferably be taken with, or shortly after a meal.

- You should avoid taking grapefruit juice, when on treatment with ISOPTIN SR 240 mg. It is important that you keep taking these tablets until your doctor tells you to stop.

Your doctor will tell you how long treatment with ISOPTIN SR 240 mg will last. Do not stop treatment early because your condition may get worse. If you have the impression that the effect of ISOPTIN SR 240 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ISOPTIN SR 240 mg than you should

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

If you do take too much ISOPTIN SR 240 mg, the following clinical signs and symptoms may appear:

- serious drop in blood pressure,
- heart failure,
- irregular heartbeat, which may lead to cardiovascular shock and cardiac arrest,
- loss of consciousness, possibly progressing to coma,
- increase in blood glucose levels,
- lowering of blood potassium levels,
- reduction in pH of the blood (metabolic acidosis),
- lack of oxygen in the body tissue (hypoxia),
- cardiovascular shock with an accumulation of water in the lungs (pulmonary oedema),
- impaired kidney function,
- spasms.

If you forget to take ISOPTIN SR 240 mg

If you forget to take one of your doses, take another as soon as you remember, but only if you remember on the same day as the missed dose. If not, do not take the missed dose at all.

DO NOT DOUBLE THE DOSE TO MAKE UP FOR FORGOTTEN INDIVIDUAL DOSES.

4. Possible side effects

ISOPTIN SR 240 mg can have side effects.

If any of the following happens, stop taking ISOPTIN SR 240 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ISOPTIN SR 240 mg. 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:

- neuropathy (numbness or weakness due to nerve damage or dysfunction),
- bradycardia (slow heartbeat),
- onset of heart failure or deterioration of pre-existing heart failure,
- excessive drop in blood pressure and/or disorders caused by drop in blood pressure when changing the body position from lying or sitting to standing (orthostatic dysregulation),
- flushing (reddening of the face with sensation of warmth),
- hypotension (low blood pressure characterised by dizziness or light-headedness),
- erythromelalgia (painful redness and swelling of the limbs),
- accumulation of fluid in the hands, ankles or feet (peripheral oedema),
- palpitations (irregular heartbeat),
- tachycardia (fast heartbeat),
- probably allergy-induced inflammation of the liver (hepatitis) with an increase in liver-specific enzymes,
- paralysis,
- hyperkalaemia (high potassium levels in your blood characterised by an irregular heartbeat and chest pain),

- atrioventricular block (1st, 2nd and 3rd degree) (serious cardiac conduction disorders),
- heart failure (characterised by shortness of breath and swelling of the feet or legs due to fluid accumulation),
- sinus arrest,
- asystole (cardiac arrest),
- bronchospasm (difficulty in breathing due to bronchial smooth muscle spasm),
- dyspnoea (shortness of breath),
- angioedema (swollen tissue, especially in the face),
- Steven-Johnson syndrome (severe allergic skin reaction with serious impact on general condition),
- erythema multiforme (red, often itchy spots which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea),
- purpura (spots or patches on the skin or mucosa due to bleeding), kidney failure.

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

Tell your doctor if you notice any of the following:

Common side effects:

- dizziness or giddiness,
- headaches,
- anxiety,
- constipation,
- nausea (feeling sick).

Uncommon side effects:

- reduced glucose tolerance,
- stomach pain,
- fatigue.

Rare side effects:

- paraesthesia (tingling or numbness if the hands and feet),
- tremor (shakiness),
- drowsiness,
- tinnitus (ringing in the ears),
- vomiting,
- hyperhidrosis (increased sweating).

Very rare side effects:

- photodermatitis (skin reactions similar to sunburn),
- worsening of certain muscle disorders (Myasthenia gravis, Lambert-Eaton syndrome, advance Duchenne muscular dystrophy).

Side effects with unknown frequency:

- extrapyramidal symptoms (abnormal involuntary movements),
- cramps,
- vertigo (dizziness),
- stomach discomfort,
- gingival hyperplasia (overgrowth of gum tissue),
- ileus (intestinal obstruction),
- alopecia (hair loss),
- maculopapular exanthema (rash with spots and bumps on the surface of the skin),
- arthralgia (joint pain),
- muscular weakness,
- myalgia (muscular pain),
- erectile dysfunction,
- galactorrhoea (unusual secretion of breast milk),
- gynaecomastia (enlargement of male breast tissue),
- increased prolactin values in the blood (characterised by a milky nipple discharge).

Not all side effects reported for ISOPTIN SR 240 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISOPTIN SR 240 mg, please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ISOPTIN SR 240 mg.

5. How to store ISOPTIN SR 240 mg

- KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
- Store ISOPTIN SR 240 mg at or below 25 °C.
- Do not use after the expiry date.
- Protect from moisture/light.
- Return any unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ISOPTIN SR 240 mg contains

- The active substance is verapamil hydrochloride.
- The other ingredients are hypromellose, indigo carmine aluminium compound, macrogol 400, macrogol 600, magnesium stearate, microcrystalline cellulose, montan glycol wax, povidone, purified water quinoline yellow, sodium alginate, talc and titanium dioxide.

What ISOPTIN SR 240 mg looks like and contents of the pack

A light green, oblong film coated tablet with a single score-line.

Packs containing either 30 or 100 sustained release tablets in amber glass bottles.

Packs of 30 film-coated tablets in PVC/PVDC/Aluminium blisters.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Botswana	B9305405	S2
Ghana	FDA/SD.183-2096	Prescription Only Medicine
Kenya	4477	Prescription Only Medicine
Mauritius	R4120/02/14	Prescription Only Medicine
Namibia	90/7.1.4/0068	NS2
Zimbabwe	97/12.6/3277	Prescription Preparations (P.P.)

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