PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ISOPTIN 40 mg film-coated tablets

Verapamil hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking ISOPTIN 40 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ISOPTIN 40 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 40 mg is and what it is used for
2. What you need to know before you take ISOPTIN 40 mg
3. How to take ISOPTIN 40 mg
4. Possible side effects
5. How to store ISOPTIN 40 mg
6. Contents of the pack and other information.

1. What ISOPTIN 40 mg is and what it is used for

ISOPTIN 40 mg contains verapamil hydrochloride and belongs to a group of medicines called calcium channel blockers.

ISOPTIN 40 mg is used to treat:

- Angina pectoris (chest pain) (with poor blood flow to the heart).
- Fast heart rate.

2. What you need to know before you take ISOPTIN 40 mg

Do not take ISOPTIN 40 mg:

- If you are hypersensitive (allergic) to verapamil hydrochloride or any of the other ingredients of ISOPTIN 40 mg (listed in section 6).
- If you have a problem with the electrical system that makes your heartbeat and controls its rate and rhythm.
- If you have recently suffered a heart attack.
- If your blood pressure is extremely low and is associated with cardiovascular 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 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) syndrome or Lown-Ganong-Levine syndrome.
- If you are already taking medicine containing ivabradine for the treatment of certain heart conditions.
- If you are taking beta-blockers to treat high blood pressure or heart conditions.

Warnings and precautions

Take special care with ISOPTIN 40 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 40 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.
- Medicines to control chest pain such as short-and long-acting nitrates.
- 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.

ISOPTIN 40 mg with food, drink and alcohol

- Avoid alcohol while using ISOPTIN 40 mg. ISOPTIN 40 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 40 mg. This may increase your risk of side effects from ISOPTIN 40 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 ISOPTIN 40 mg.

Pregnancy

The effects of ISOPTIN 40 mg on your unborn baby are not known. ISOPTIN 40 mg crosses the placenta and can be detected in umbilical vein blood at delivery.

Breastfeeding

ISOPTIN 40 mg can pass into your breast milk. You should not breastfeed while taking ISOPTIN 40 mg.

Driving and using machines

It is not always possible to predict to what extent ISOPTIN 40 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 40 mg affects you. ISOPTIN 40 mg increases alcohol levels in the blood, therefore you will not have to drink as much alcohol for your blood levels to be above the legal limit to drive.

ISOPTIN 40 mg contains sodium

ISOPTIN 40 mg contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially sodium free.

3. How to take ISOPTIN 40 mg

Do not share medicines prescribed for you with any other person.
Always take ISOPTIN 40 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The average daily dose is 120 mg – 360 mg in three divided doses where possible.

The doses of ISOPTIN 40 mg as prescribed by the physician, are to be taken regularly, preferably half an hour before meals together with some liquid.
Your doctor will tell you how long treatment with ISOPTIN 40 mg will last. Do not stop treatment early because your condition may get worse. If you have the impression that the effect of ISOPTIN 40 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ISOPTIN 40 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 40 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 40 mg

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ISOPTIN 40 mg

Do not interrupt or discontinue treatment with ISOPTIN 40 mg without discussing this in advance with your doctor,

ISOPTIN 40 mg should not be stopped suddenly after long-term treatment, but discontinued gradually.

4. Possible side effects

ISOPTIN 40 mg can have side effects.

Not all side effects reported for ISOPTIN 40 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISOPTIN 40 mg, please consult your health care provider for advice.

If any of the following happens, stop taking ISOPTIN 40 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 40 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),
- severe facial pain,
- bradycardia (slowed 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),
- reddening of the face with sensation of warmth (flushing),
- low blood pressure (hypotension),
- erythromelalgia (painful redness and swelling of the limbs),
- accumulation of fluid in the hands, ankles or feet (peripheral oedema),
- palpitations (fast or irregular heartbeats),
- tachycardia (fast heartbeat),
- probably allergy-induced inflammation of the liver (hepatitis) with an increase in liver-specific enzymes,
- paralysis,
- atrioventricular block (1st, 2nd and 3rd degree) (serious cardiac conduction disorders),
- sinoatrial block,
- heart failure (cardiac insufficiency),
- sinus arrest,
- sinus bradycardia,
- 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,
- feeling sick (nausea).

Uncommon side effects:

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

Rare side effects:

- paraesthesia (tingling or numbness if the hands and feet),
- mild 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:

- hypersensitivity (allergic reaction),
- extrapyramidal symptoms (abnormal involuntary movements),
- tetraparesis (weakness in the arms and legs),
- cramps,
- hyperkalaemia (excessive blood potassium concentrations),
- vertigo (dizziness),
- abdominal discomfort,
- gingival hyperplasia (overgrowth of gum tissue),
- burning sensations of the gums,
- ileus (intestinal obstruction),
- alopecia (hair loss),
- pruritis (itching),
- maculopapular exanthema (rash with spots and bumps on the surface of the skin),
- urticaria (hives),
- temporary skin rash,
- arthralgia (joint pain),
- muscular weakness,
- myalgia (muscular pain),
- increased urination,
- erectile dysfunction,
- galactorrhoea (unusual secretion of breast milk),
- gynaecomastia (enlargement of male breast tissue),
- increased prolactin values in the blood.
- Laboratory abnormalities: Reversible increase of transaminases and/or alkaline phosphatase has been observed and is most probably a response of allergic hepatitis.

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

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 40 mg.

5. How to store ISOPTIN 40 mg

- KEEP ALL MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN.
- Store at or below 30 °C, in a cool, dry place.
- Protect from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ISOPTIN 40 mg contains

- The active substance is verapamil hydrochloride.
- The other ingredients are calcium hydrogen phosphate dihydrate, colloidal anhydrous silica, croscarmellose sodium, hypromellose (type 2910, viscosity 3mPa-s), macrogols (type 6000), magnesium stearate, microcrystalline cellulose, sodium laurilsulfate, talc, titanium dioxide E 171.

What ISOPTIN 40 mg looks like and contents of the pack

White, biconvex film-coated tablets. Embossed with "40" on one side and with the "Knoll" triangle

on the other side.

Hard PVC/PVDC colourless, transparent film and aluminium foil, printed or unprinted face for PVC film for 100 film-coated tablets per pack.

Holder of Certificate of Registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof 1709

South Africa

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Registration number:

South Africa: H646 (act 101/1965)

Country	Registration number	Distribution Category
Botswana	B9305390	S2
Ghana	FDA/SD.183-2095	Prescription Only Medicine
Kenya	4277	Prescription Only Medicine
Namibia	14/7.1.4/0337	NS2

NAME AND ADDRESS OF MANUFACTURER

Famar A.V.E Anthoussa

Anthoussa Avenue 7,

Anthoussa Attiki, Greece