

Isoptin® SR 240mg Prolonged-Release Tablets

(verapamil hydrochloride)

Patient Information Leaflet

IMPORTANT INFORMATION

- * Read all of this leaflet carefully before you start taking this medicine
- * Keep this leaflet as you may need to read it again
- * This leaflet provides a summary of the information currently available about Isoptin SR
- * For further information or advice ask your doctor or pharmacist
- * This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you
- * Tell your doctor or pharmacist if you experience any side effects

Leaflet contents:

- 1 What is Isoptin SR and what it is used for?
- 2 What you need to know before you take Isoptin SR
- 3 How should you take your tablets?
- 4 Possible side effects.
- 5 How should you store your tablets?
- 6 Further information.

1 What is Isoptin SR and what it is used for?

Isoptin SR tablets belong to a group of medicines called calcium channel blockers. Calcium channel blockers change the amount of calcium getting into the muscle cells in your heart and blood vessels. This can change the strength and speed with which your heart beats. It also opens up the blood vessels so blood can be pumped around the body more easily. This helps more oxygen to get to your heart muscle and can lower your blood pressure.

Isoptin SR tablets are used to treat hypertension (high blood pressure) and to prevent angina (chest pain) attacks.

The active ingredient in Isoptin SR tablets is verapamil hydrochloride.

2 What you need to know before you take Isoptin SR

Do not take Isoptin SR if:

- * you are sensitive (allergic) to verapamil or any of the ingredients in the tablets? (See Section 6)
- * your blood pressure is extremely low as a result of heart problems (such as during shock)
- * you have recently had a severe heart attack
- * you have heart failure or second or third degree heart block (impaired nerve signal in the heart – causing a very slow heartbeat) or an electrical abnormality of the heart (atrial fibrillation/flutter) causing periods of very fast heartbeat (Wolff-Parkinson-White syndrome)
- * you have problems with your heart valves or ‘sick sinus syndrome’ (irregular heartbeat)

Warnings and precautions

Talk to your doctor or pharmacist before taking Isoptin SR if:

- * you have ever suffered from heart failure, first degree AV block or an irregular heart beat
- * you have very low blood pressure
- * you have liver or kidney disease
- * you are being treated with injectable beta-blockers (except in an intensive care situation)
- * you have any neuromuscular diseases e.g. myasthenia gravis, Lambert-Eaton Syndrome or advanced Duchenne muscular dystrophy

Other medicines and Isoptin SR tablets

Tell your doctor or pharmacist if you are taking have recently taken or might take any of the following medicines:

- * beta-blockers used to treat high blood pressure and heart conditions (these include propranolol and metoprolol)
- * alpha blockers used to treat high blood pressure, heart conditions and prostate disorders (these include prazosin and terazosin)
- * medicines known as “statins” such as atorvastatin, lovastatin, simvastatin used to lower cholesterol levels
- * any other medicine for high blood pressure or an abnormal heart beat (arrhythmia) such as flecainide, quinidine, digoxin and digitoxin
- * medicines used to treat depression (including the herbal product St John’s Wort), anxiety or psychosis. These may include imipramine, buspirone and lithium.
- * medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection.

- * glyburide, used to treat certain types of diabetes
- * aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever
- * almotriptan, used to treat migraine
- * midazolam, used as a sedative or anaesthetic
- * theophylline, used to treat asthma
- * doxorubicin, an anti-cancer medicine
- * cimetidine, used to treat indigestion or stomach ulcers
- * carbamazepine or phenobarbital (phenobarbitone). These medicines are used as anti-convulsants.
- * rifampicin, used to treat tuberculosis and other types of infection
- * zidovudine, used to treat HIV
- * erythromycin, clarithromycin, and telithromycin, used to treat certain types of infection
- * colchicine or sulfinpyrazone, used to treat gout.

Tell your surgeon or dentist that you are taking Isoptin SR if surgery is planned as it may affect the anaesthetic used.

Isoptin SR with food and drink and alcohol

Do **NOT** drink grapefruit juice whilst taking your tablets as it can affect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.

Isoptin can increase the amount of alcohol in the body and the time it takes for alcohol to leave the body. You should avoid excessive amounts of alcohol whilst you are being treated with Isoptin.

Pregnancy, breast feeding and fertility

Please discuss with your doctor if you are pregnant, planning to become pregnant or are breast feeding. The safety of Isoptin SR in pregnancy is not known

Driving and using machines

Do **NOT** drive, operate machinery or do anything that requires you to be alert, until you know how the tablets affect you. Isoptin SR can make some people feel dizzy and tired.

Isoptin SR 240mg Prolonged-Release tablets contain up to 32mg (1.39mmol) of sodium and this should be taken into consideration before taking your medicine.

3 How should you take your tablets?

ALWAYS take your tablets exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist.

TAKE YOUR TABLETS with a glass of water. You should swallow the tablets without chewing or crushing them. It does not matter if you have not eaten, so they can be taken with or without food.

The number of tablets that you will need to take will depend on what you are being treated for:

ADULTS:

Hypertension (high blood pressure)

The usual dose is one Isoptin SR a day. If you have not taken Isoptin SR before, your doctor may prescribe a lower dose such as a half Isoptin SR tablet each day. The maximum dose to treat high blood pressure is 480mg each day. This is usually taken as one Isoptin SR in the morning and one in the evening leaving a gap of about 12 hours between each dose.

Elderly: The usual starting dose is half a tablet each morning. Your doctor may choose to increase this dose if needed.

Angina (chest pain):

The usual starting dose for angina is one Isoptin SR taken twice a day. You should take one tablet in the morning and one in the evening, with a gap of about 12 hours in between them. Your doctor may prescribe a lower dose according to your symptoms.

If you take more tablets than prescribed (an overdose) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your tablets with you.

If you forget to take your tablets take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

Isoptin® SR 240mg Prolonged-Release Tablets

(verapamil hydrochloride)

Patient Information Leaflet (continued)

If you stop taking your tablets your condition may get worse. It is important that you keep taking these tablets until your doctor tells you to stop. Do **NOT** stop just because you feel better.

Other things to remember about Isoptin SR

- * Isoptin SR tablets may be broken in half if your doctor advises you to do so (e.g. if a lower dose has been prescribed).
- * The tablets should **NOT** be crushed or chewed, as this will affect the modified-release formulation of the product.

4 Possible side effects

Like all medicines, Isoptin SR can cause side effects, although not everybody gets them. **If you experience any unusual symptoms whilst taking your tablets, tell your doctor or pharmacist.**

Tell your doctor IMMEDIATELY if you experience any of the following side effects:

- * Yellowing of the skin or eyes, a fever or tenderness around the tummy. These are signs that your liver may not be functioning as well as usual
- * Palpitations, chest pains for the first time or chest pains becoming more frequent, swollen ankles, hot and painful hands or feet
- * Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue or severe skin rash. These may be symptoms of an allergic reaction.

Other side effects of Isoptin SR may include:

- * allergic reactions
- * increased blood sugar levels
- * nervousness
- * headache, dizziness, a tingling or prickling feeling on the skin, tremor and movement disorders
- * reduced sense of touch and nerve damage
- * drowsiness
- * vertigo
- * a ringing sound in the ears (tinnitus)
- * irregular heartbeat, heart attack and heart failure
- * low blood pressure
- * flushing of the face or neck
- * burning pain, redness and swelling of the hands, feet or other extremities
- * difficulty breathing
- * nausea and vomiting
- * constipation and bowel obstruction
- * swollen gums which start to spread over the teeth
- * stomach pain, discomfort and swelling
- * red or itchy skin rash
- * sensitivity to light
- * hair loss (alopecia)
- * aches and pains in the joints and/or muscles and muscle weakness
- * impotence
- * breast enlargement or swelling
- * breasts that leak milk
- * tiredness
- * increase in liver enzymes
- * greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to produce milk
- * problems with an artificial pacemaker

5 How should you store your tablets?

Do **NOT** take your tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month. Keep your tablets in the original pack. Do not store above 25°C. Your tablets should be stored in a safe place out of the reach and sight of children, your medicine could harm them. If your doctor decides to stop your treatment, return any leftover tablets to your pharmacist. Only keep the tablets if your doctor tells you to. 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

The active ingredient in Isoptin SR tablets is verapamil hydrochloride, in a prolonged release (slow release) formulation.

What Isoptin SR 240mg Prolonged-Release Tablets look like:

Isoptin SR tablets are light green, oblong in shape and marked with two triangles on one side. Each tablet contains 240 mg of verapamil hydrochloride.

The tablets are available in packs of 30.

Other tablet ingredients:

Microcrystalline cellulose, sodium alginate, povidone, magnesuim stearate, purified water, hypromellose, macrogol 400, macrogol 6000, talc, titanium dioxide (E171), quinoline yellow (E104), indigo carmine (E132), glycol wax.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

AbbVie Deutschland GmbH & Co. KG, Knollstrasse 67061 Ludwigshafen, Germany.

Isoptin is a registered trademark of ABBOTT GmbH & CO. KG

Revision date: 17/04/14

POM

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.