

Package leaflet: Information for the patient

Isoptin SR 240mg® Prolonged-Release Tablets (verapamil hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

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

1. WHAT ISOPTIN SR IS 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 heart attack (within the last 7 days)
- 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 or Lown-Ganong-Levine syndrome)
- you have problems with your heart valves or “sick sinus syndrome” (irregular heartbeat) and do not have a pacemaker
- you are being treated with ivabradine (for heart conditions)

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, digitoxin and disopyramide
- 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, phenytoin or phenobarbital (phenobarbitone). These medicines are used as anti-convulsants.
- rifampicin, used to treat tuberculosis and other types of infection
- ritonavir, used to treat HIV
- erythromycin, clarithromycin, and telithromycin, used to treat certain types of infection
- colchicine or sulfinpyrazone, used to treat gout.
- dabigatran, (medicine to prevent the formation of blood clots)
- ivabradine, used to treat heart conditions
- medicines known as “direct oral anticoagulants” such as dabigatran, apixaban, rivaroxaban and edoxaban
- metformin. Verapamil may decrease the glucose-lowering effect of metformin.

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 contains sodium

This medicine contains 37.1 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.9 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ISOPTIN SR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

TAKE YOUR TABLETS with a glass of water. You should swallow the tablets without chewing or crushing them. It is recommended to take the tablets with or shortly after meals.

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 Isoptin SR than you should (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 Isoptin SR 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.

If you stop taking Isoptin SR 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, this medicine can cause side effects, although not everybody gets them.

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.

Common (may affect up to 1 in 10 people)

- dizziness
- headache
- slow heartbeat
- flushing
- low blood pressure
- constipation
- nausea (feeling sick)
- swollen feet or ankles

Uncommon (may affect up to 1 in 100 people)

- irregular or fast heartbeat
- stomach pain
- tiredness

Rare (may affect up to 1 in 1,000 people)

- a tingling or prickling feeling on the skin
- tremor
- drowsiness
- a ringing sound in the ears (tinnitus)
- being sick
- sweating a lot more than usual

Other side effects (frequency cannot be estimated from the available data)

- allergic reactions
- increased blood sugar levels
- high potassium levels
- movement disorders
- paralysis
- seizures
- nervousness
- reduced sense of touch and nerve damage
- vertigo
- heart attack
- heart failure
- unusual heartbeat
- burning pain, redness and swelling of the hands, feet or other extremities

- difficulty in breathing
- stomach discomfort
- swollen gums which start to spread over the teeth
- bowel obstruction
- liver problems
- swelling of the mouth, lips or tongue or severe skin rash
- rash
- sensitivity to light
- hair loss (alopecia)
- itching
- aches and pains in the joints and/or muscles and muscle weakness
- kidney problems
- impotence
- breast enlargement or swelling
- greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to produce/leak milk
- increase in liver enzymes
- problems with an artificial pacemaker

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ISOPTIN SR

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION.

What Isoptin SR tablets contains:

The active substance verapamil hydrochloride, in a prolonged release (slow release) formulation. Each tablet contains 240 mg of verapamil hydrochloride.

The other ingredients are sodium alginate, microcrystalline cellulose, povidone, talc, titanium dioxide (E171), hypromellose, macrogol, magnesium stearate, montan glycol wax. In addition, Isoptin SR tablets contain quinoline yellow (E104), indigo carmine (E132).

What Isoptin SR tablets look like and contents of the pack:

Isoptin SR tablets are light green, oblong in shape and marked with two triangles on one side. The tablets are available in calendar packs of 28.

Marketing Authorisation Holder: Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13.

Manufacturer: FAMAR A.V.E. Anthoussa Plant, 7, Anthoussa Avenue, 153 49, Attiki, Athens, Greece.

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