

Package leaflet: Information for the patient

Isoptin 40mg® Film-Coated Tablets **Isoptin 80mg® Film-Coated Tablets** **Isoptin 120mg® Film-Coated 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 is and what it is used for
2. What you need to know before you take Isoptin tablets
3. How to take Isoptin tablets
4. Possible side effects
5. How to store Isoptin tablets?
6. Contents of the pack and other information

1. WHAT ISOPTIN IS AND WHAT IT IS USED FOR

Isoptin 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 tablets are used to treat hypertension (high blood pressure), abnormal heart rhythms and to prevent and treat angina (chest pain) attacks.

The active ingredient in Isoptin tablets is verapamil hydrochloride.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOPTIN TABLETS

Do not take Isoptin tablets if:

- your blood pressure is extremely low as a result of severe heart problems (such as during shock)
- 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 injectable beta-blockers
- you are sensitive (allergic) to verapamil or any of the ingredients in the tablets? (See Section 6)
- you are pregnant or planning to become pregnant

- you are being treated with ivabradine (for heart conditions)

Warnings and precautions

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

- you have ever suffered from heart failure, or first degree AV block or an irregular heart beat
- you have had a recent heart attack
- you have very low blood pressure
- you have liver or kidney disease
- you have any neuromuscular diseases e.g. myasthenia gravis, Lambert- Eaton Syndrome or advanced Duchenne muscular dystrophy

Other medicines and Isoptin 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.
- glyburide, used to treat certain types of diabetes
- aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever
- midazolam, used as a sedative or anaesthetic
- medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection
- 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
- almotriptan, used to treat migraine
- 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

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

Isoptin tablets 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.

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 can make some people feel dizzy and tired.

Isoptin tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE ISOPTIN TABLETS?

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. The tablets should be taken with or shortly after meals. You should swallow the tablets without chewing or crushing them.

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 for hypertension is 40 – 120 mg of Isoptin taken three to four times a day. The maximum dose is 480 mg each day, to be taken in divided doses, as directed by your doctor.

Angina (chest pain)

The dose for angina is 80 – 120 mg of Isoptin taken three to four times a day.

Abnormal heart rhythms

The usual dose for abnormal heart rhythms is 40–120 mg taken three to four times a day.

If you take more Isoptin 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 take the tablets 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 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.

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, 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
- high potassium levels
- movement disorders
- paralysis
- seizures
- nervousness
- vertigo
- heart attack
- heart failure
- unusual heartbeat
- flushing of the face or neck
- 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
- swelling of the mouth, lips or tongue or severe skin rash
- rash
- 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

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ISOPTIN

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.

This medicinal product does not require any special storage conditions.

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 Tablets contains:

The active substance is verapamil hydrochloride. Isoptin tablets are available in three different strengths containing either 40 mg, 80 mg or 120 mg of verapamil hydrochloride.

The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, hypromellose, sodium laurilsulfate macrogol, talc and titanium dioxide (E171).

What Isoptin Tablets look like and contents of the pack:

Isoptin 40mg Film-coated Tablets are circular, biconvex, white, film-coated tablets, embossed "40" on one side and embossed with a triangle on the other side.

Isoptin 80mg Film-coated Tablets are circular, biconvex, white film-coated tablets, embossed 'Isoptin 80' on one side and 'Knoll' above the scoreline on the other side.

Isoptin 120mg Film-coated tablets are circular, biconvex, white, film-coated tablets, embossed 'Isoptin 120' on one side and 'Knoll' above the scoreline on the other side.

Isoptin 80mg film-coated tablets and Isoptin 120mg film-coated tablets have a score line to allow breaking for ease of swallowing.

The tablets are available in blister strips in cartons containing 100 tablets.

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

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

FAMAR A.V.E. Anthoussa Plant, 7 Anthoussa Avenue, 153 49 Anthoussa, Attiki, Greece (40mg and 80mg film-coated Tablets only).

This leaflet was last revised in