

Package leaflet: Information for the patient

Isoptin 2.5mg/ml Solution for Injection or Infusion (verapamil hydrochloride)

Read all of this leaflet carefully before you receive 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, ward 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 2.5mg/ml Solution for Injection or Infusion is and what it is used for
2. What you need to know before you receive Isoptin 2.5mg/ml Solution for Injection or Infusion
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1. WHAT ISOPTIN 2.5MG/ML SOLUTION FOR INJECTION OR INFUSION IS AND WHAT IT IS USED FOR

Isoptin 2.5mg/ml Solution for Injection or Infusion belongs 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 2.5mg/ml Solution for Injection or Infusion is used to treat abnormal heart rhythms such as an irregular or rapid heart rate. It may also be used to treat severe hypertension (high blood pressure) and severe angina (chest pain).

The active ingredient in Isoptin 2.5mg/ml Solution for Injection or Infusion is verapamil hydrochloride.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE ISOPTIN 2.5MG/ML SOLUTION FOR INJECTION OR INFUSION

Do not take Isoptin 2.5mg/ml Solution for Injection or Infusion 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 before taking Isoptin 2.5mg/ml Solution for Injection or Infusion if:

- you have ever suffered from heart failure, or first degree AV block or an irregular heart beat
- 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 2.5mg/ml Solution for Injection or Infusion

Tell your doctor 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
- Rifampicin, used to treat tuberculosis and other types of infection
- Carbamazepine or Phenobarbital (Phenobarbitone). These medicines are used as anti-convulsants
- Ritonavir, used to treat HIV
- Erythromycin, clarithromycin and telithromycin, used to treat types of infection
- Colchicine or sulfinpyrazone used to treat gout
- Almotriptan, used to treat migraine
- Dabigatran, used to thin the blood
- Ivabradine, used to treat heart conditions
- medicines known as “direct oral anticoagulants” such as dabigatran, apixaban, rivaroxaban and edoxaban

Isoptin 2.5mg/ml Solution for Injection or Infusion with food and drink and alcohol

Do **NOT** drink grapefruit juice whilst taking Isoptin 2.5mg/ml Solution for Injection or Infusion as it can effect the absorption of this medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.

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 medicine affects you.

Isoptin can make some people feel dizzy and tired.

Isoptin 2.5mg/ml Solution for Injection or Infusion contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 2ml ampoule, that is to say essentially 'sodium-free'.

3. HOW YOU WILL RECEIVE ISOPTIN 2.5MG/ML SOLUTION FOR INJECTION OR INFUSION

Isoptin 2.5mg/ml Solution for Injection or Infusion is given to you by injection into a vein (Intravenously). This will be carried out by a doctor.

The dose will vary according to your condition. This will be decided by the doctor. The medical team in the hospital may monitor your blood pressure and ECG (the electrical activity of the heart) throughout your treatment. The usual doses are as follows

Adults:

5 mg by slow intravenous injection over a period of 2 minutes.

If necessary, an extra 5 mg may be injected after 5 to 10 minutes. The solution may then be given as an infusion at a dose of 5-10mg per hour, on average up to a total dose of 100mg per day.

For elderly patients the dose should be administered over at least 3 minutes.

Children:

Newborns; 0.75 to 1 mg (0.3 to 0.4 ml of injection solution).

Infants: 0.75 to 2 mg (0.3 to 0.8 ml of injection solution).

Aged 1–5 years: 2 to 3 mg (0.8 to 1.2 ml of injection solution).

Aged 6–14 years: 2.5 to 5 mg (1 to 2 ml of injection solution).

Intravenous infusion in hypertensive crisis (severe high blood pressure):

Initially 0.05-0.1 mg/kg per hour. This dose may be increased, if necessary, after 30-60 minutes. The average total dose is up to 1.5 mg/kg per day.

This medicinal product contains less than 1 mmol sodium (23 mg) per 2 ml vial, i.e. essentially 'sodium-free'

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following rare side effects tell your doctor IMMEDIATELY:

- 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
- movement disorders
- paralysis
- seizures
- high potassium levels
- 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 breathing
- stomach discomfort
- swollen gums which start to spread over the teeth
- bowel obstruction
- hepatitis (inflammation of the liver) symptoms of which include feeling or being sick,
- loss of appetite, fever, weakness, tiredness, and stomach pain
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA 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 2.5MG/ML SOLUTION FOR INJECTION OR INFUSION

Do not store above 30°C. Keep the ampoules in the outer carton in order to protect from light. The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection. It should NOT be used after the expiry date printed on the label. Keep out of the sight and reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Isoptin 2.5mg/ml Solution for Injection or Infusion contains:

Each ampoule of injection solution contains 2.5 mg per ml verapamil hydrochloride in water for injections and sodium chloride, with hydrochloric acid 10% as pH adjuster.

What Isoptin 2.5mg/ml Solution for Injection or Infusion looks like and contents of the pack:

Isoptin 2.5mg/ml Solution for Injection or Infusion is a clear, colourless solution. Your doctor will not use this product if it does not match this description.

The product is available in 2 ml ampoules, each containing 5 mg of verapamil hydrochloride

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

Manufacturer: FAMAR HEALTH CARE SERVICES MADRID S.A.U. Avda. de Leganés, 62 28923 Alcorcón-Madrid Spain

This leaflet was last revised in