

ISOPTIN® INJECTION

verapamil hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Isoptin Injection.

It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Isoptin Injection against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor.

Keep this leaflet in a safe place.

You may need to read it again.

What Isoptin Injection is used for

Isoptin Injection is used to:

- treat unusual fast heart beat
- treat high blood pressure, also called hypertension
- treat poor blood flow to the heart
- prevent certain heart problems occurring during surgery

Your doctor may have prescribed Isoptin Injection for another reason. Ask your doctor if you have any questions about why Isoptin Injection has been prescribed for you.

Isoptin Injection belongs to a group of medicines called calcium channel blockers or calcium antagonists. They work by widening blood vessels which lets more blood and oxygen reach the heart and at the same time lowers high blood pressure. Isoptin Injection also helps control fast heart rate.

Isoptin does not change the amount of calcium in your blood or bones. Calcium in your diet or in calcium supplements will not interfere with the way Isoptin Injection works.

Isoptin is available only with a doctor's prescription.

Isoptin Injection is not addictive.

Before you are given Isoptin Injection

When you must not be given it

You should not be given Isoptin Injection if you have an allergy to verapamil hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You should not be given Isoptin Injection if you:

- have certain heart conditions (such as heart failure, very slow heart rate, heart conduction problems, some irregular heartbeats or disease of the heart muscle).
- are taking any of the following medications, or medications containing these ingredients:
 - ivabradine

- Direct Oral Anticoagulants (DOACs) such as dabigatran (in certain situations)
- beta-blockers,

- have low blood pressure, also called hypotension.

You should not be given Isoptin Injection after the expiry date printed on the pack.

You should not be given Isoptin Injection if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given Isoptin Injection, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Isoptin Injection is not recommended for use during pregnancy, particularly the first 6 months. If there is a need to consider Isoptin Injection during the last 3 months of your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Isoptin Injection is not recommended while you are breastfeeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- recent heart attack
- any other heart condition
- liver disease
- kidney disease
- tumour in the head
- high or low blood pressure
- muscle conditions such as Duchenne muscular dystrophy, myasthenia gravis, Lambert-Eaton syndrome

If you have not told your doctor about any of the above, tell them before you are given Isoptin Injection.

Taking other medicines

Several medicines can cause unwanted reactions if used with Isoptin.

Ask your doctor or pharmacist for advice before being given this medicine.

In particular tell your doctor if you are taking any of the following medicines:

Medicines to treat heart problems or high blood pressure:

- Beta-blockers e.g. atenolol, propranolol, metoprolol, etc
- Ivabradine
- Digoxin
- Any other medicines used to control an irregular heart beat e.g. quinidine, flecainide, disopyramide
- Diuretics (also called fluid tablets).
- Any other medicines used to control high blood pressure (especially prazosin or terazosin)

Medicines used to lower cholesterol:

- Statins such as atorvastatin or simvastatin

Medicines used to treat or prevent blood clots (sometimes referred to as "blood thinners"):

- Direct Oral Anticoagulants (DOACs) such as dabigatran
- Aspirin

Medicines used to treat or prevent gout:

- Colchicine or sulfinpyrazone

Medicines used to treat psychological problems:

- Any medicines to treat depression, or psychosis. Such as imipramine, buspirone, midazolam or lithium

Medicines to treat epilepsy or seizures:

- Phenytoin, carbamazepine, phenobarbital.

Medicines to treat or prevent organ transplant rejection:

- Cyclosporin, everolimus, sirolimus, tacrolimus

Medicines used to treat infections or tuberculosis:

- such as erythromycin, clarithromycin, telithromycin or rifampicin

Medicines used in surgical procedures:

- General anaesthetics used for inducing sleep
- Muscle relaxants e.g. dantrolene

Medicines used in the treatment of Human Immunodeficiency Virus (HIV):

- Such as ritonavir.

Other medicines that may react with Isoptin Injection:

- theophylline, a medicine used to treat asthma
- doxorubicin, a medicine used to treat certain cancers
- cimetidine, a medicine commonly used to treat stomach ulcers and reflux
- metformin and glibenclamide, medicines used to treat diabetes
- aspirin

Avoid alcohol while using Isoptin. You may experience greater blood pressure lowering effects than usual.

Avoid grapefruit juice, as this may increase the blood levels of verapamil.

These medicines may be affected by Isoptin Injection, or may affect how well it works. You may need different amounts of your medicine or you may need to take or use different medicines. Your doctor will advise you.

This is not a complete list of medicines which may interfere with Isoptin.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal remedies, including those obtained without a prescription from a pharmacy, supermarket or health food shop.

How Isoptin Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

Isoptin Injection is given as a slow injection or "drip" injection into a vein (intravenously). The doctor will continuously check your heart rate and blood pressure while you are being given Isoptin Injection.

Isoptin Injection must only be given by a doctor.

Overdose

As Isoptin Injection is most likely given to you in hospital by a doctor, it is very unlikely that you will receive too much.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

While you are being given Isoptin Injection

Your doctor and nursing staff are trained to look after you while you are being given Isoptin Injection.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Isoptin Injection.

Like all other medicines, Isoptin Injection may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following:

- constipation
- bloating
- nervousness, dizziness, light-headedness
- feeling sick, vomiting
- headache
- tiredness
- shakiness
- pins and needles
- muscular weakness or muscle and joint pains
- flushing
- buzzing, hissing, whistling, ringing or other persistent noise in the ears
- unexpected secretion of breast milk
- breast enlargement in men
- impotence (inability to get or maintain an erection)
- increased skin sensitivity to sunlight
- enlarged gums

Tell your doctor immediately if you notice any of the following:

- chest pain
- difficulty in breathing, wheezing or coughing
- rash, itching or hives on the skin
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- swelling of the hands, ankles or feet
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- throbbing and burning pain in the hands and feet with redness of the skin
- bleeding under the skin or tissues

- fast or irregular heartbeats
- shortness of breath, and swelling of the feet or legs due to fluid build up

Other side effects not listed above may occur in some patients. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything that is making you feel unwell.

After using Isoptin Injection

Storage

Isoptin Injection will be stored in the pharmacy or on the ward at a temperature below 25 degrees Celsius.

Further information

This is not all the information available on Isoptin Injection. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product description

What it looks like

Isoptin Injection is a clear colourless solution in a clear glass ampoule.

Ingredients

Active ingredient:

- verapamil hydrochloride 5 mg per 2 mL

Other ingredients:

- sodium chloride
- hydrochloric acid
- water for injections

Isoptin Injection is available in the following strength and pack:

5 mg in 2 mL, 5 x 2 mL ampoules

Supplier

Isoptin ampoules are supplied by:

Mylan Health Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
Australia

www.mylan.com.au

Phone: 1800 314 527

Australian registration number:

AUST R 12796

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