NEW ZEALAND CONSUMER MEDICINE INFORMATION

ISOPTIN[®]

verapamil hydrochloride solution for injection, 5 mg/2 mL

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 or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Isoptin Injection is used for

Isoptin is used to treat

- an unusually fast heart beat
- irregular heart beat (also known as arrhythmia)
- high blood pressure (also called hypertension)
- poor blood flow to the heart

Isoptin can also be used to prevent certain heart problems occurring during surgery.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Isoptin contains the active ingredient verapamil hydrochloride. It belongs to a group of medicines called calcium

channel blockers or calcium antagonists.

It works by widening blood vessels which lets more blood and oxygen reach the heart and at the same time lowers high blood pressure. Isoptin also helps control fast heart rate.

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

Isoptin Injection is not addictive.

This medicine is available only with a doctor's prescription.

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:

- any medicine containing verapamil hydrochloride
- 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

- have low blood pressure, also called hypotension
- are taking ivabradine (a medicine used to treat chest pain)

You should not be given Isoptin Injection after the expiry date printed on the pack or 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, foods, preservatives or dyes.

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

- recent heart attack
- any other heart problem
- blood vessel (circulatory) disease or a stroke
- muscle conditions such as Duchenne muscular dystrophy, myasthenia gravis, Lambert-Eaton syndrome
- kidney or liver problems
- tumour in the head

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Isoptin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Isoptin may interfere with each other. These include:

- medicines to treat heart problems or high blood pressure including betablockers such as atenolol or propranalol
- diuretics (also called fluid tablets)
- any other medicines used to control an irregular heartbeat or high blood pressure e.g. digoxin, digitoxin, quinidine, flecainide, disopyramide
- medicines used to lower cholesterol, such as atorvastatin or simvastatin
- medicines to treat depression, anxiety or psychosis such as imipramine, buspirone, midazolam or lithium
- medicines to treat epilepsy or seizures, such as phenytoin, carbamazepine and phenobarbitone
- medicines to treat or prevent organ transplant rejection, such as such as ciclosporin, everolimus, sirolimus and tacrolimus
- medicines used to treat infections or tuberculosis, such as erythromycin, clarithromycin or rifampicin
- medicines used in the treatment Human Immunodeficiency Virus (HIV) such as ritonavir
- medicines used to treat or prevent gout such as colchicine
- medicines used in surgical procedures such as general anaesthetics used for inducing sleep muscle relaxants
- medicines used to prevent blood clots.

Other medicines that may react with Isoptin:

- 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
- glibenclamide or metformin, medicines used to treat diabetes
- aspirin or dabigatran
- almotriptan, a medicine that treat migraine headaches
- St John's Wort, a herbal medicine used to treat depression

These medicines may be affected by Isoptin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

While taking Isoptin, you should also avoid

- Alcohol as you may experience greater blood pressure lowering effects than usual
- grapefruit juice, as this may increase the blood levels of verapamil

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Isoptin Injection is given

Isoptin injection must only be given by the doctor.

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

How much is injected

Your doctor will decide how much Isoptin you will receive. This depends on your condition and other factors, such as your weight.

If too much is injected (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.

National Poisons Information Centre (0800 POISON or 0800 764 766) for advice.

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 or pharmacist as soon as possible if you do not feel well while you are being given Isoptin Injection.

Like all medicines, Isoptin 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 side effects.

As with most medicines, if you are over 65 years of age you may have an increased chance of getting side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation
- bloating
- nervousness, dizziness, light-headedness

- feeling sick, vomiting, upset stomach
- headache
- tiredness
- shakiness
- pins and needles
- muscular weakness or muscle or joint pains
- 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
- excessive sweating
- drowsiness
- flushing

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- chest pain, fainting, collapse
- slow, fast or irregular heartbeat
- shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet and legs
- 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
- fever
- severe blisters, skin rash, itching or flaking skin, bleeding in the lips, eyes, mouth, nose and genitals (Steven Johnson Syndrome)
- throbbing and burning pain in the hands and feet with redness of the skin
- bleeding under the skin or tissues

Do not be alarmed by this list of side effects. You may not experience any of them.

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.

After using Isoptin Injection

Storage

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

Product description

What it looks like

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

Ingredients

<u>Active ingredient:</u> Isoptin injection contains 2.5 mg/mL of verapamil hydrochloride as the active ingredient.

Inactive ingredients: Isoptin injection also contains:

- sodium chloride
- water for injections
- hydrochloric acid for pH adjustment.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Isoptin is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

7 September 2023 (Based on datasheet dated 7 September 2023).

ISOPTIN[®] is a Viatris company trade mark.