

ISOPTIN[®] injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ISOPTIN injection?

ISOPTIN injection contains the active ingredient verapamil hydrochloride. ISOPTIN injection is used to treat unusual fast heart beat, treat high blood pressure, also called hypertension, treat poor blood flow to the heart and prevent certain heart problems occurring during surgery.

For more information, see Section [1. Why am I using ISOPTIN injection?](#) in the full CMI.

2. What should I know before I use ISOPTIN injection?

Do not use if you have ever had an allergic reaction to ISOPTIN injection or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ISOPTIN injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ISOPTIN injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ISOPTIN injection?

- ISOPTIN injection must only be given by a doctor. More instructions can be found in Section [4. How do I use ISOPTIN injection?](#) in the full CMI.

5. What should I know while using ISOPTIN injection?

Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol while on ISOPTIN injection.• You may experience greater blood pressure lowering effects than usual.
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Looking after your medicine	<ul style="list-style-type: none">• ISOPTIN injection will be stored in the pharmacy or on the ward at a temperature below 25 degrees Celsius.
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For more information, see Section [5. What should I know while using ISOPTIN injection?](#) in the full CMI.

6. Are there any side effects?

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, increased skin sensitivity to sunlight or 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ISOPTIN[®] injection

Active ingredient(s): verapamil hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using ISOPTIN injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ISOPTIN injection.**

Where to find information in this leaflet:

- [1. Why am I using ISOPTIN injection?](#)
- [2. What should I know before I use ISOPTIN injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ISOPTIN injection?](#)
- [5. What should I know while using ISOPTIN injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ISOPTIN injection?

ISOPTIN injection contains the active ingredient verapamil hydrochloride. 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 injection 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 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 is not addictive.

2. What should I know before I use ISOPTIN injection?

Warnings

You should not be given ISOPTIN injection if:

- you are allergic 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

Always check the ingredients to make sure you can use this medicine.

- 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).
- You have low blood pressure, also called hypotension.
- You 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

- **The packaging is torn or shows signs of tampering.**

Check with 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

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

Several medicines can cause unwanted reactions if used with ISOPTIN injection.

- **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

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ISOPTIN injection.

4. How do I use ISOPTIN injection?

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.

5. What should I know while using ISOPTIN injection?

Your doctor and nursing staff are trained to look after you while you are being given ISOPTIN injection.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol while on ISOPTIN injection. You may experience greater blood pressure lowering effects than usual.

Storage

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• constipation• bloating• nervousness, dizziness, light-headedness• feeling sick, vomiting• headache• tiredness• shakiness• pins and needles	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain ● difficulty in breathing, wheezing or coughing ● rash, itching or hives on the skin 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

7. Product details

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

What ISOPTIN injection contains

Active ingredient (main ingredient)	verapamil hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• hydrochloric acid

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|--|--|
| | <ul style="list-style-type: none">• water for injections |
|--|--|

Do not take this medicine if you are allergic to any of these ingredients.

What ISOPTIN injection looks like

ISOPTIN injection a clear colourless solution in a clear glass ampoule. (AUST R 12796).

Who distributes ISOPTIN injection

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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