

ISOPTIN[®] AND ISOPTIN SR[®]

Verapamil hydrochloride



What is in this leaflet

This leaflet answers some common questions about Isoptin.

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 taking 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 is used for

There are two types of Isoptin:

- Isoptin (40 mg and 80 mg tablets)
- Isoptin SR (120 and 240 mg tablets)

The letters SR in the name Isoptin SR stand for "sustained release". This means the medicine is released into the blood over an extended period of time, usually allowing the medicine to be taken only once a day.

Depending on your condition, your doctor will prescribe Isoptin or Isoptin SR.

In most parts of this leaflet, the name Isoptin is used to refer to both Isoptin tablets and Isoptin SR tablets. Where there is information specific to the type of Isoptin, the separate names are used.

Isoptin is used in the treatment of:

- high blood pressure, also called hypertension
- angina (chest pain)
- irregular heartbeats, also called arrhythmias

Isoptin is also used in patients who have recently had a heart attack.

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

Isoptin belongs to a group of medicines called calcium channel blockers or calcium antagonists. They work by opening up blood vessels, which lets more blood and oxygen reach the heart and at the same time lowers high blood pressure. Isoptin tablets also help to control irregular heartbeats.

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 works.

Isoptin SR is not recommended for use in children under the age of 18, as there have been no studies of its effects in this age group.

Isoptin is available only with a doctor's prescription.

Before you take Isoptin

When you must not take it

Do not take Isoptin 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.

Do not take Isoptin if you:

- have certain heart conditions such as heart failure, a very slow heart rate, irregular heart beat or disease of the heart muscle
- have low blood pressure (also called hypotension)
- are taking ivabradine (a medicine used to treat chest pain)

Do not use Isoptin after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Isoptin contact your doctor.

Before you start to take 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:

- 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

Tell your doctor if you are pregnant or plan to become

pregnant.

Isoptin may affect your baby if you take it in pregnancy. Your doctor will discuss the possible risks and benefits of taking Isoptin during pregnancy.

Tell your doctor if you are breastfeeding.

Isoptin passes into breast milk. Your doctor will discuss the possible risks and benefits of taking Isoptin when breastfeeding.

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 interact with each other. These include:

- medicines to treat heart problems or high blood pressure including beta-blockers such as atenolol or propranolol
- diuretics (also called fluid tablets)
- any other medicines used to control an irregular heart beat or high blood pressure e.g. digoxin, 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 ciclosporin, everolimus, sirolimus and tacrolimus
- medicines used to treat infections or tuberculosis,

such as erythromycin, clarithromycin or rifampicin medicines used in the treatment of 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
- 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 and metformin, medicines used to treat diabetes
- aspirin, dabigatran or other blood thinning medicines
- almotriptan, a medicine used to treat migraine
- St John's Wort, a product used to elevate mood

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. Your doctor will advise you.

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

While taking Isoptin, you should avoid:

- Alcohol, as you may experience greater effects of alcohol 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 to take Isoptin

Follow all directions given to you by your doctor or pharmacist

carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.***How much to take***

Your doctor will tell you how many tablets you will need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

Isoptin tablets are usually taken two or three times a day.

Isoptin SR tablets are usually taken once daily or they may be taken twice daily.

Follow all directions given to you by your doctor carefully.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew Isoptin SR tablets. If you crush or chew Isoptin SR tablets they will not work as well.

Isoptin SR tablets 240 mg can be broken in half if your doctor has prescribed half a tablet.

Do not halve Isoptin SR 120 mg tablet.

When to take it

Take your medicine at about the same time(s) each day. Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

Take Isoptin and Isoptin SR with or shortly after meals.

How long to take it

Treatment with Isoptin is usually long term. Keep taking Isoptin for as long as your doctor recommends.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and

take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Isoptin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Isoptin, you may have a slow heartbeat, chest pain, difficulty breathing, feel very faint or collapse.

While you are taking Isoptin

Things you must do

If you become pregnant while taking Isoptin, tell your doctor.

Tell all doctors, dentists and pharmacists who are treating you, or before any surgery that you are taking Isoptin.

If you are being treated for angina, tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Isoptin.

Visit your doctor regularly so that they can check on your progress.

Your doctor may ask you to have blood tests to check your liver from time to time.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Isoptin.

Things you must not do

Do not take Isoptin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful getting up from a sitting position. Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful driving or operating machinery until you know how Isoptin affects you. Do not drive, operate machinery or do anything else that could be dangerous if you are tired, dizzy or lightheaded.

If you drink alcohol while taking Isoptin, dizziness or lightheadedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Isoptin.

Like all other 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 of the 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 more common side effects and they worry you:

- constipation

- dizziness
- feeling sick, upset stomach
- headache
- tiredness
- flushing

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

- chest pain, fainting, collapse
- slow, fast, or irregular heart beat
- shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet and legs
- fever
- severe blisters, skin rash, itching or flaking skin

Do not be alarmed by this list of possible 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

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep Isoptin tablets in a cool dry place where the temperature stays below 25°C.

Do not store Isoptin or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your tablets where children cannot reach them.

Disposal

If your doctor tells you to stop taking Isoptin, or the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Isoptin is available as:

Isoptin 40 mg: white, biconvex film coated tablet with "40" (side 1) and "Knoll-triangle" (side 2).

Isoptin 80 mg: white biconvex film coated tablet with "Isoptin 80" (side 1) and "Knoll" (side 2, scored).

Each pack of Isoptin 40 mg and 80 mg contains 100 tablets.

Isoptin SR is available as:

Isoptin SR 120 mg: White, biconvex and film coated tablet with "120 SR" embossed on one side and "Knoll" on the other side.

Each pack of Isoptin SR 120 mg contains 100 tablets.

Isoptin SR 240 mg: Light green, capsule shaped, scored, film coated tablets with a double "Knoll triangle" on one side.

Each pack of Isoptin SR 240 mg contains 30 tablets.

Ingredients

The active ingredient in Isoptin is verapamil hydrochloride. Isoptin tablets contain either 40 mg or 80 mg of verapamil hydrochloride. Isoptin tablets also contain:

- calcium hydrogen phosphate
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- colloidal silica dioxide
- hypromellose
- purified talc
- sodium lauryl sulfate
- macrogol 6000
- titanium dioxide

Isoptin SR tablets contain either 120 mg or 240 mg verapamil hydrochloride. Isoptin SR tablets also contain:

- microcrystalline cellulose
- sodium alginate
- povidone
- magnesium stearate
- hypromellose
- Macrogol 400
- Macrogol 6000
- purified talc
- titanium dioxide
- glycol montanite

Isoptin SR 240 mg also contains:

- quinoline yellow (CI 47005)
- indigo carmine (CI 73015)

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

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