

APO-IVABRADINE

Ivabradine hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about ivabradine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of taking ivabradine 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 this medicine is used for

Ivabradine is used to treat:

- symptomatic stable angina in adult patients whose heart rate is over or equal to 70 beats per minute (bpm)
- heart failure

Stable angina:

Stable angina typically occurs when you exert yourself and is usually relieved with medication or rest.

Angina is a pain or uncomfortable feeling in the chest. This pain or feeling can also spread to the arms and neck and sometimes also to the shoulders and back. Angina is caused

by too little blood and oxygen getting to the heart.

Ivabradine relieves stable angina by lowering the heart rate. Ivabradine is not for the relief of a sudden attack of angina. Your doctor will have given you other medication to treat this.

Heart failure:

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Some people develop heart failure after having had a heart attack.

However, there are also other causes of heart failure.

Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get tired easily after light physical activity such as walking. You may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. In severe heart failure, symptoms may occur even at rest.

Ivabradine helps to treat heart failure. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired, and have less swelling.

Ask your doctor if you have any questions about why ivabradine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Ivabradine can only be obtained with a doctor's prescription.

Ivabradine is not addictive.

Before you take this medicine

When you must not take it

Do not take ivabradine if you have an allergy to:

- ivabradine
- any of the other ingredients listed at the end of this leaflet

Do not take ivabradine if you have or have had the following medical conditions:

- disturbances of heart rhythm, sick sinus syndrome or sino-atrial block
- certain type of artificial pacemaker
- 3rd degree Atrioventricular (AV) block
- a resting heart rate below 70 beats per minute prior to treatment
- unstable or acute heart failure
- very low blood pressure
- unstable angina
- cardiogenic shock (sudden and severe drop in blood pressure and blood flow through the body because the heart is not pumping normally)

- heart attack
- severe liver disease
- Hypertrophic Cardiomyopathy (HOCM)

Do not take this medicine if you are pregnant or breastfeeding, trying to become pregnant, or are of childbearing age and are not using reliable birth control

Ivabradine may affect your developing baby if you take it during pregnancy. Ivabradine passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you are taking any of the following medications:

- ketoconazole, an oral antifungal therapy
- diltiazem or verapamil, used to treat high blood pressure or angina
- macrolide antibiotics, including azithromycin, clarithromycin, erythromycin and roxithromycin
- cyclosporin, used to prevent rejection following transplants
- gestodene
- anti-retroviral drugs used to treat HIV infections.

Do not take ivabradine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to 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:

- an artificial pacemaker. People with a certain type of artificial pacemaker should not use ivabradine. Your doctor will be

able to tell you whether you can use ivabradine with your pacemaker

- a slow heart beat (less than 70 beats per minute)
- a particular heart condition with an abnormal electrical signal called 'long QT syndrome'
- symptoms of atrial fibrillation, a heart condition where the pulse at rest is unusually high (over 110 beats per minute) or irregular without any apparent reason
- low blood pressure
- a recent stroke
- unstable heart failure
- severe heart failure or heart failure with an abnormal electrical signal called 'bundle branch block'
- severe liver disease
- moderate or severe kidney disease
- an eye condition called 'retinitis pigmentosa', a condition that affects the light sensitive cells on the inner portion of the eye.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 foods can interfere with the action of ivabradine by increasing or decreasing its effect. This includes:

- grapefruit and grapefruit juice
- macrolide antibiotics (e.g. azithromycin, clarithromycin, erythromycin and roxithromycin)
- cyclosporin (used to prevent rejection following transplants)
- ketoconazole (an oral antifungal therapy)
- gestodene
- medicines to treat HIV infections

- rifampicin (an antibiotic)
- barbiturates (for difficulty sleeping or epilepsy)
- phenytoin (for epilepsy)
- beta-blockers (e.g. atenolol, propranolol or metoprolol for high blood pressure, heart rhythm disorders, or angina pectoris)
- quinidine, disopyramide, ibutilide, sotalol, amiodarone (for heart rhythm disorders)
- certain types of medicines to treat depression (e.g. imipramine)
- certain types of medicines to treat anxiety, schizophrenia or other psychoses (e.g. phenothiazines and thioridazine)
- some medicines of the calcium channel blocker class (e.g. diltiazem and verapamil)
- some herbal remedies (e.g. St John's Wort)
- some types of 'fluid' or 'water tablets' used to treat high blood pressure or fluid retention, which may cause a decrease in blood potassium level (e.g. frusemide, hydrochlorothiazide and indapamide)

You may need different amounts of your medication or to take different medicines. Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking ivabradine.

Other medicines not listed above may interact with ivabradine.

How to take this medicine

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Swallow the tablets whole with a full glass of water. This medicine should be taken with food.

How to take it

For stable angina:

The starting dose should not exceed one tablet of ivabradine 5 mg taken twice a day. After three to four weeks of starting treatment, and during ongoing treatment, your doctor may review your dose and may adjust it depending on your condition. The maintenance dose should not exceed one tablet of ivabradine 7.5 mg taken twice daily.

For heart failure:

The usual starting dose is one tablet of ivabradine 5 mg taken twice a day. After two weeks of starting treatment, and during ongoing treatment, your doctor may review your dose and may adjust it depending on your condition. The maintenance dose should not exceed one tablet of ivabradine 7.5 mg taken twice daily.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking ivabradine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ivabradine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include a very slow heartbeat, breathlessness or tiredness.

While you are using this medicine

Things you must do

If you are about to be started on any new medicines, remind your doctor or pharmacist that you are taking ivabradine.

Tell any other doctors, dentists or pharmacists who treat you that you are taking ivabradine.

Avoid drinking grapefruit juice while you are taking ivabradine.

If you are taking ivabradine for stable angina, tell your doctor if you continue to have angina attacks or if they become more frequent while you are using ivabradine.

Tell your doctor well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who

admits you that you are using ivabradine.

If you discover you are pregnant while taking ivabradine, tell your doctor immediately.

Things you must not do

Do not use ivabradine to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful when driving or operating machinery in situations where there may be sudden changes in dim to bright lighting.

Side effects

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

Ivabradine helps most people with symptoms of stable angina or heart failure, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and if they worry you:

- temporary visual symptoms

Some patients taking ivabradine may see bright spots of light, a halo, coloured flashes or multiple or distorted images. This may occur particularly when moving quickly between dim and bright lighting conditions.

These visual symptoms are usually mild and appear in the first two months of treatment, and then disappear as treatment continues. Tell your doctor or pharmacist if they bother you.

Be careful when driving or operating machinery in situations where there may be sudden changes in dim to bright lighting.

Blurred vision, double vision or impaired vision may also occur.

- palpitations and extra heart beats, irregular rapid contraction of the heart, abnormal perception of heartbeat, low or uncontrolled blood pressure, unusually slow or fast heartbeat
- nausea, constipation, diarrhoea, abdominal pain
- headache
- fainting (possibly related to slow heart rate)
- spinning sensation (vertigo)
- difficulty breathing (dyspnoea)
- muscle cramps
- feeling tired or weak
- dizziness, light headedness (a symptom of low blood pressure possibly related to slow heart rate), generally feeling unwell
- abnormal ECG heart tracing.

Ivabradine may cause changes in laboratory tests including high blood levels of uric acid, an excess of eosinophils (a type of white blood cell) and elevated creatinine in blood (a breakdown product of muscle).

Tell your doctor if you notice anything else that makes you feel unwell.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty in breathing
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- rash, redness of the skin, itching, itchy rash.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

After taking this medicine

Storage

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

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

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

Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can reduce the quality of medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one and a-half metres above floor level is a good place to store medicines.

Disposal

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

Product description

What it looks like

APO-IVABRADINE 5mg:

Light salmon coloured, capsule shaped, biconvex, film-coated tablet scored on one side. AUST R: 285496

APO-IVABRADINE 7.5mg:

Light salmon coloured, round, biconvex, film-coated tablet. AUST R: 285493

APO-Ivabradine 5mg and APO-Ivabradine 7.5mg tablets are supplied in a blister strip, in packs containing 14 or 56 tablets.

Ingredients

Each APO-Ivabradine 5mg tablet contains 5mg of ivabradine, as the hydrochloride salt.

Each APO-Ivabradine 7.5mg tablet contains 7.5mg of ivabradine, as the hydrochloride salt.

APO-Ivabradine also contains the following:

- lactose monohydrate
- magnesium stearate
- starch maize
- maltodextrin
- colloidal anhydrous silica.
- OPADRY II complete film coating system 31F240016 ORANGE.

Sponsor

Generic Partners Pty Ltd
Level 1, 313 Burwood Road
Hawthorn VIC 3122

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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