

APO-IVABRADINE

ivabradine (as the hydrochloride) 5mg & 7.5mg film coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APO-IVABRADINE.

It does not contain all the available information.

Reading this leaflet 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 APO-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 APO-IVABRADINE is

The name of your medicine is APO-IVABRADINE. It contains the active ingredient ivabradine (I-vab'-rah- deen).

What APO-IVABRADINE is used for

You may be prescribed APO-IVABRADINE for:

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

APO-IVABRADINE relieves stable angina by lowering the heart rate.

APO-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.

APO-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.

APO-IVABRADINE can only be obtained with a doctor's prescription.

There is no evidence that APO-IVABRADINE is addictive.

Ask your doctor if you have any questions about why APO-IVABRADINE has been prescribed for you.

Before you take APO-IVABRADINE

When you must not take it

There are some people who should not take APO-IVABRADINE. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please talk to your doctor or pharmacist.

Do not use APO-IVABRADINE if you:

- **have an allergy to ivabradine hydrochloride, the active substance in APO-IVABRADINE, or to any of the other ingredients listed at the end of this leaflet**
- **have disturbances of heart rhythm; a "sick sinus syndrome" or sino-atrial block**
- **have a certain type of artificial pacemaker**
- **have 3rd degree Atrioventricular (AV) block**

- **have a resting heart rate below 70 beats per minute prior to treatment**
- **have unstable or acute heart failure**
- **have very low blood pressure**
- **have unstable angina**
Unstable angina is a pain or uncomfortable feeling in the chest that lasts longer than a few minutes or occurs with rest, and may not be relieved with medication
- **have cardiogenic shock**
Which is a sudden and severe drop in blood pressure and blood flow through the body because the heart is not pumping normally
- **are having a heart attack**
- **are taking any of the following medications:**
 - ketoconazole, an oral antifungal therapy
 - diltiazem or verapamil, used to treat high blood pressure or angina
 - antibiotics of the macrolide class, including azithromycin, clarithromycin, erythromycin and roxithromycin
 - cyclosporin, used to prevent rejection following transplants
 - gestodene and anti-retroviral drugs such as medicines to treat HIV infections.
- **have severe liver disease**
- **suffer from Hypertrophic Cardiomyopathy (HOCM)**
- **are pregnant, or trying to become pregnant**
- **are of childbearing age and are not using reliable birth control**
APO-IVABRADINE may affect your developing baby if you take it during pregnancy
- **are breastfeeding.**

Do not give this medicine to anyone else.

Do not use APO-IVABRADINE if the packaging is torn or shows signs of tampering. If the packaging is damaged when you

first receive the product, return it to your pharmacist.

Do not take APO-IVABRADINE if the expiry date (EXP) printed on the pack has passed.

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

Tell your doctor if:

- **you are pregnant, or trying to become pregnant**
- **you are of childbearing age and are not using reliable birth control**
- **you are breastfeeding or plan to breast-feed as breastfeeding should be discontinued if you take APO-IVABRADINE**
- **you have or have had any medical conditions, especially the following:**
 - an artificial pacemaker. People with a certain type of artificial pacemaker should not use APO-IVABRADINE. Your doctor will be able to tell you whether you can use APO-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'
 - allergies to any other medicines or any foods, dyes or preservatives
 - 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.

Your doctor may want to take special precautions if you have any of these conditions.

If you think any of these situations apply to you, or you have any doubts or questions about taking APO-IVABRADINE talk to your doctor or pharmacist.

Taking other medicines

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

Some medicines and foods can interfere with the action of APO-IVABRADINE by increasing or decreasing its effect. You may need different amounts of your medication or to take different medicines. The medicines that interact with APO-IVABRADINE include the following:

- grapefruit and grapefruit juice
- antibiotics of the macrolide class, including 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 (like atenolol, propranolol, metoprolol, etc, for high blood pressure, heart rhythm disorders, or angina pectoris)
- quinidine, disopyramide, ibutilide, sotalol (to treat heart rhythm disorders)

- certain types of medicines to treat depression (such as imipramine)
- certain types of medicines to treat anxiety, schizophrenia or other psychoses (such as phenothiazines and thioridazine)
- amiodarone (for heart rhythm disorders)
- some medicines of the calcium channel blocker class, including diltiazem and verapamil
- some herbal remedies such as 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, such as frusemide, hydrochlorothiazide, Indapamide.

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking APO-IVABRADINE.

How to take APO-IVABRADINE

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 to take it

Swallow your tablets with water, and with food. The usual dose is one tablet in the morning and one tablet in the evening. In some cases, for example if you are elderly, your doctor may prescribe half the dose i.e. one half of a APO-IVABRADINE 5 mg tablet in the morning and one half of a APO-IVABRADINE 5 mg tablet in the evening.

How much to take

For stable angina:

The starting dose should not exceed one tablet of APO-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 APO-IVABRADINE 7.5 mg taken twice daily.

For heart failure:

The usual starting dose is one tablet of APO-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 APO-IVABRADINE 7.5 mg taken twice daily.

Your doctor will tell you what dose to take.

When to take it

Take one tablet in the morning and one tablet at night.

How long to take it for

You should take APO-IVABRADINE until your doctor tells you to stop taking it.

If you are not sure how long to take it for, talk to your doctor.

The dose of APO-IVABRADINE you need will be decided and adjusted by your doctor. In all cases, strictly follow your doctor's directions.

If you think that the effect of APO-IVABRADINE is too strong or too weak, talk to your doctor or pharmacist.

If you forget to take APO-IVABRADINE

If you forget to take a dose, take the next dose at your normal time.

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

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

If you take more APO-IVABRADINE than you should (overdose)

If you think that you or anyone else may have taken too much APO-IVABRADINE, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident & Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The general effects of taking an overdose of APO-IVABRADINE is a very slow heartbeat. You may feel breathless or tired.

If you have this symptom when you take APO-IVABRADINE, tell your doctor.

While you are taking APO-IVABRADINE

Things you must do

Follow your doctor's instructions about how many tablets to take, and when to take them.

Avoid drinking grapefruit juice while you are taking APO-IVABRADINE.

If you do not follow your doctor's instructions, you may not get the benefits from treating your angina or heart failure.

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

Tell all doctors, dentists or pharmacists who treat you that you are using APO-IVABRADINE.

Tell your doctor or pharmacist that you are taking APO-IVABRADINE if you are about to be started on any new medicines.

If you discover you are pregnant while taking APO-IVABRADINE, tell your doctor immediately.

Things you must not do

Do not use APO-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 APO-IVABRADINE.

APO-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 (very common side effect). Some patients taking APO-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.

APO-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 the following signs occur then tell your doctor immediately or go to the accident and emergency department 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.

These side effects are not common but can become serious.

After taking APO-IVABRADINE

Storage

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.

Heat and dampness can reduce the quality of medicines.

Keep APO-IVABRADINE in a cool dry place where the temperature stays below 25 degrees C, but not in the fridge or freezer.

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.

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

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

Disposal

If your doctor tells you to stop taking APO-IVABRADINE or the tablets have passed their

expiry date, return the unused medicines to your pharmacist.

Product description

What it looks like

APO-IVABRADINE 5mg:

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

APO-IVABRADINE 7.5mg:

Light salmon coloured, round, biconvex, film-coated tablet.

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 inactive ingredients:

Tablet Core:

Lactose monohydrate, magnesium stearate, starch maize, maltodextrin, colloidal anhydrous silica.

Film-coating:

OPADRY II complete film coating system 31F240016 ORANGE.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian Registration Number:

APO-IVABRADINE 5mg tablet
AUSTR: 285496

APO-IVABRADINE 7.5mg tablet
AUSTR: 285493

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