

APO-IVABRADINE

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 APO-IVABRADINE?

APO-IVABRADINE contains the active ingredient ivabradine (hydrochloride).

APO-IVABRADINE is used to treat symptomatic stable angina or heart failure.

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

2. What should I know before I use APO-IVABRADINE?

Do not use if you have ever had an allergic reaction to ivabradine or any of the ingredients listed at the end of the CMI, have a "sick sinus syndrome (sino-atrial block), certain type of pacemaker, a third degree AV block, a resting heartrate below 70 bpm before treatment, unstable or acute heart failure, very low blood pressure, unstable angina, cardiogenic shock, having a heart attack, taking certain medications, have sever liver disease suffer from Hypertrophic Cardiomyopathy, are pregnant or trying to get pregnant, or of childbearing age and not using reliable birth control, are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with APO-IVABRADINE and affect how it works. 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.

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 APO-IVABRADINE?

- Swallow your tablets with water, and with food.
- The usual dose is one tablet in the morning and one tablet in the evening.
- Take APO-IVABRADINE exactly as your doctor has prescribed.
- More instructions can be found in Section [4. How do I use APO-IVABRADINE?](#) in the full CMI.

5. What should I know while using APO-IVABRADINE?

Things you should do	<ul style="list-style-type: none">• Avoid drinking grapefruit juice.• Tell your doctor if you continue to have angina attacks or if they become more frequent.• Tell your doctor well in advance of any expected hospitalisation or surgery.• Tell your immediately doctor if you become pregnant while taking APO-IVABRADINE.
Things you should not do	<ul style="list-style-type: none">• Do not take APO-IVABRADINE to treat any other conditions unless your doctor says so.• Do not give this medicine to anyone else, even if their symptoms are similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Be careful when driving or operating machinery in situations where there may be sudden changes in dim to bright lighting.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-IVABRADINE Tablets in a cool dry place where the temperature is below 25°C.

For more information, see Section [5. What should I know while using APO-IVABRADINE?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The serious side effects are: signs of allergy. The common side effects are temporary visual symptoms (bright spots of light, a halo, coloured flashes or multiple or distorted images).

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.

APO-IVABRADINE

Active ingredient: *ivabradine (as the hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-IVABRADINE tablets. 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 APO-IVABRADINE against the benefits this medicine is expected to have for you.

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 APO-IVABRADINE.

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

Where to find information in this leaflet:

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

1. Why am I using APO-IVABRADINE?

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.

2. What should I know before I use APO-IVABRADINE?

Warnings

Do not use APO-IVABRADINE if:

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.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - heart problems, including heart failure
 - liver problems.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given APO-IVABRADINE.

Your doctor will advise you whether or not to take APO-IVABRADINE or if you need to adjust the dose or adapt your treatment.

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 plan 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.

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.

Some medicines may be affected by APO-IVABRADINE 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.

In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- 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 have more information on medicines to be careful with or avoid while taking APO-IVABRADINE.

4. How do I use APO-IVABRADINE?

Take Ivabradine tablets exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They 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

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 / use APO-IVABRADINE

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

How to take APO-IVABRADINE?

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.

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 use 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 use too much APO-IVABRADINE

If you think that you have used too much APO-IVABRADINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

5. What should I know while using APO-IVABRADINE?

Things you should 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 should not do

- Do not take APO-IVABRADINE to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you

Driving or using machines

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

Effects of food

Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including APO-IVABRADINE.

Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking APO-IVABRADINE may increase the effects of this medicine.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep APO-IVABRADINE tablets in the original pack until it is time to take them.
- Keep APO-IVABRADINE tablets in a cool dry place where the temperature is below 25°C but not in the fridge or freezer.

Do not store APO-IVABRADINE, or any other medicine, in the bathroom or near a sink.

Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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. Blurred vision, double vision or impaired vision may also occur. 	<p>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.</p> <p>Be careful when driving or operating machinery in situations where there may be sudden changes in dim to bright lighting.</p>
<ul style="list-style-type: none"> • 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. 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you</p>

<ul style="list-style-type: none"> • indigestion • sexual problems. <p>Effects on Laboratory tests:</p> <ul style="list-style-type: none"> • 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). 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> <p>These may or may not be due to APO-IVABRADINE but you should tell your doctor.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Call your doctor straight away or go to the accident and emergency department at your nearest hospital if you notice any of these serious side effects.</p> <p>These side effects are not common but can become serious.</p>

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

Other side effects not listed here may occur in some people.

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available with a doctor's prescription.

What APO-IVABRADINE contains

Active ingredient (main ingredient)	Ivabradine hydrochloride
Other ingredients (inactive ingredients)	<p>APO-IVABRADINE tablets contain:</p> <p>Tablet Core:</p> <ul style="list-style-type: none"> • Lactose monohydrate • magnesium stearate • starch maize • maltodextrin • colloidal anhydrous silica. <p>Film-coating:</p> <ul style="list-style-type: none"> • OPADRY II complete film coating system 31F240016 ORANGE.
Potential allergens	Lactose

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

What APO-IVABRADINE looks like

APO-IVABRADINE is available in two strengths.

APO-IVABRADINE 5 tablets- Light salmon coloured, capsule shaped, biconvex, film-coated tablet scored on one side. (AUST R 285496)

The tablets are available in blister pack of 56 tablets.

APO-IVABRADINE 7.5 tablets - Light salmon coloured, round, biconvex, film-coated tablet. (AUST R 285493).

The tablets are available in blister pack of 56 tablets.

Who distributes APO-IVABRADINE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in October 2024