

Ivabradine 5mg and 7.5mg Film-coated Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Ivabradine 5mg and 7.5mg Film-coated Tablets but within the leaflet it will be referred to as Ivabradine Tablets.

What is in this leaflet

- 1 What Ivabradine Tablets are and what they are used for**
- 2 What you need to know before you take Ivabradine Tablets**
- 3 How to take Ivabradine Tablets**
- 4 Possible side effects**
- 5 How to store Ivabradine Tablets**
- 6 Contents of the pack and other information**

1 What Ivabradine Tablets are and what they are used for

Ivabradine Tablets contain the active substance ivabradine. Ivabradine is a heart medicine used to treat:

- Symptomatic stable angina pectoris (which causes chest pain) in adult patients whose heart rate is over or equal to 70 beats per minute. It is used in adult patients who do not tolerate or cannot take heart medicines called beta-blockers. It is also used in combination with beta-blockers in adult patients whose condition is not fully controlled with a beta-blocker.
- Chronic heart failure in adult patients whose heart rate is over or equal to 75 beats per minute. It is used in combination with standard therapy, including beta-blocker therapy or when beta-blockers are contraindicated or not tolerated.

About stable angina pectoris (usually referred to as “angina”)

Stable angina is a heart disease which happens when the heart does not receive enough oxygen. The most common symptom of angina is chest pain or discomfort.

About chronic heart failure

Chronic heart failure is a heart disease which happens when your heart cannot pump enough blood to the rest of your body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

How Ivabradine Tablets work

The specific heart rate lowering action of ivabradine helps:

- to control and reduce the number of angina attacks by lowering heart’s need for oxygen,
- to improve the heart functioning and vital prognosis in patients with chronic heart failure.

2 What you need to know before you take Ivabradine Tablets

Do not take Ivabradine Tablets

- if you are allergic to ivabradine or any of the other ingredients of this medicine (listed in section 6)
- if your resting heart rate before treatment is too slow (below 70 beats per minute)
- if you are suffering from cardiogenic shock (a heart condition treated in hospital)
- if you are having a heart attack
- if you suffer from very low blood pressure
- if you suffer from severe liver problems
- if you suffer from a heart rhythm disorder (sick sinus syndrome, sino-atrial block, AV-block of 3rd degree)
- if you have heart failure which has recently become worse
- if your heartbeat is exclusively imposed by your pacemaker
- if you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion)
- if you are already taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as clarithromycin, josamycin, telithromycin or erythromycin given orally), medicines to treat HIV infections (such as nelfinavir, ritonavir) or nefazodone (medicine to treat depression) or diltiazem, verapamil (used for high blood pressure or angina pectoris)
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ivabradine Tablets

- if you suffer from heart rhythm disorders (such as irregular heartbeat, palpitation, increase in chest pain) or sustained atrial fibrillation (a type of irregular heartbeat), or an abnormality of electrocardiogram (ECG) called ‘long QT syndrome’
 - if you have symptoms such as tiredness, dizziness or shortness of breath (this could mean that your heart is slowing down too much)
 - if you suffer from symptoms of atrial fibrillation (pulse rate at rest unusually high (over 110 beats per minute) or irregular, without any apparent reason, making it difficult to measure)
 - if you have had a recent stroke (cerebral attack)
 - if you suffer from mild to moderate low blood pressure
 - if you suffer from uncontrolled blood pressure, especially after a change in your antihypertensive treatment
 - if you suffer from severe heart failure or heart failure with abnormality of ECG called ‘bundle branch block’
 - if you suffer from chronic eye retinal disease
 - if you suffer from moderate liver problems
 - if you suffer from severe renal problems.
- If any of the above applies to you, talk to your doctor straight away, before or while taking Ivabradine Tablets.

Children and adolescents

Do not give this medicine to children and adolescents younger than 18 years. Available data are insufficient in this age group.

Other medicines and Ivabradine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Make sure to tell your doctor if you are taking any of the following medicines, as a dose adjustment of Ivabradine Tablets or monitoring should be required:

- QT prolonging medicines to treat either heart rhythm disorders or other conditions:
 - quinidine, disopyramide, sotalol, ibutilide, amiodarone (to treat heart rhythm disorders)
 - bepridil (to treat angina pectoris)
 - certain types of medicines to treat anxiety, schizophrenia or other psychoses (such as pimozide, ziprasidone, sertindole)
 - anti-malarial medicines (such as mefloquine or halofantrine)
 - pentamidine (an antiparasitic medicine)
 - cisapride (against the gastro-oesophageal reflux)
 - intravenous erythromycin (an antibiotic)
- fluconazole (an antifungal medicine)
- rifampicin (an antibiotic)
- barbiturates (for difficult sleeping or epilepsy)
- phenytoin (for epilepsy)
- Hypericum perforatum or St John’s Wort (herbal treatment for depression)
- Some types of diuretics which may cause decrease in blood potassium level, such as furosemide, hydrochlorothiazide, indapamide (used to treat oedema, high blood pressure).

Ivabradine Tablets with food and drink

Avoid grapefruit juice during treatment with Ivabradine Tablets.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Ivabradine Tablets if you are pregnant or are planning to have a baby.

If you are pregnant and have taken Ivabradine Tablets, talk to your doctor.

Do not take Ivabradine Tablets if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take Ivabradine Tablets if you are breast-feeding. Talk to your doctor if you are breast-feeding or intending to breast-feed as breast-feeding should be discontinued if you take Ivabradine Tablets.

Driving and using machines

Ivabradine Tablets may cause temporary luminous visual phenomena (a temporary brightness in the field of vision, see “Possible side effects”). If this happens to you, be careful when driving or using machines at times when there could be sudden changes in light intensity, especially when driving at night.

Ivabradine Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Ivabradine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Ivabradine Tablets should be taken during meals. Ivabradine 5mg Tablets can be divided into equal doses.

If you are being treated for stable angina pectoris

The starting dose should not exceed one tablet of Ivabradine 5mg twice daily. If you still have angina symptoms and if you have tolerated the 5mg twice daily dose well, the dose may be increased.

The maintenance dose should not exceed 7.5mg twice daily. Your doctor will prescribe the right dose for you. The usual dose is one tablet in the morning and one tablet in the evening. In some cases (e.g. if you are aged 75 years or more), your doctor may prescribe half the dose i.e., one half Ivabradine 5mg tablet (corresponding to 2.5mg ivabradine) in the morning and one half 5mg tablet in the evening.

If you are being treated for chronic heart failure

The usual recommended starting dose is one tablet of Ivabradine 5mg twice daily increasing if necessary to one tablet of Ivabradine 7.5mg twice daily. Your doctor will decide the right dose for you. The usual dose is one tablet in the morning and one tablet in the evening. In some cases (e.g. if you are aged 75 years or more), your doctor may prescribe half the dose i.e., one half Ivabradine 5mg tablet (corresponding to 2.5mg ivabradine) in the morning and one half 5mg tablet in the evening.

If you take more Ivabradine Tablets than you should

A large dose of Ivabradine Tablets could make you feel breathless or tired because your heart slows down too much. If this happens, contact your doctor immediately.

If you forget to take Ivabradine Tablets

If you forget to take a dose of Ivabradine Tablets, take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

If you stop taking Ivabradine Tablets

As the treatment for angina or chronic heart failure is usually life-long, you should discuss with your doctor before stopping this medicinal product.

If you think that the effect of Ivabradine Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience the following serious side effect stop taking Ivabradine Tablets and seek medical help immediately:

- Swollen face, tongue or throat, difficulty in breathing or swallowing (angioedema), fainting (uncommon: may affect up to 1 in 100 people).
- Irregular rapid contraction of the heart (Atrial fibrillation), abnormal perception of heartbeat (Bradycardia, Ventricular extrasystoles, AV 1st degree block (ECG prolonged PQ interval) (common: may affect up to 1 in 10 people)

The most common adverse reactions with this medicine are dose dependent and related to its mode of action:

Very common (may affect more than 1 in 10 people):

Luminous visual phenomena (brief moments of increased brightness, most often caused by sudden changes in light intensity). They can also be described as a halo, coloured flashes, image decomposition or multiple images. They generally occur within the first two months of treatment after which they may occur repeatedly and resolve during or after treatment.

Common (may affect up to 1 in 10 people):

Modification in the heart functioning (the symptoms are a slowing down of the heart rate). They particularly occur within the first 2 to 3 months of treatment initiation.

Other side effects have also been reported:

Common (may affect up to 1 in 10 people):

Headache, dizziness, blurred vision (cloudy vision), uncontrolled blood pressure.

Uncommon (may affect up to 1 in 100 people):

Double vision, impaired vision, spinning sensation (vertigo), palpitations and cardiac extra beats, low blood pressure, difficulty breathing (dyspnoea), feeling sick (nausea), constipation, diarrhoea, abdominal pain, skin rash, muscle spasms, feeling of tiredness, feeling of weakness, an excess of eosinophils (a type of white blood cell), high blood levels of uric acid, elevated creatinine in blood (a breakdown product of muscle), abnormal ECG heart tracing.

Rare (may affect up to 1 in 1,000 people):

Skin reddening, itching, urticaria, feeling unwell.

Very rare (may affect up to 1 in 10,000 people):

Irregular heartbeats (AV 2nd degree block, AV 3rd degree block, Sick sinus syndrome).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ivabradine Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Ivabradine Tablets contain

- The active substance is ivabradine (as hydrochloride).
Ivabradine 5mg: each Film-coated tablet contains 5mg ivabradine (as hydrochloride).
Ivabradine 7.5mg: each Film-coated tablet contains 7.5mg ivabradine (as hydrochloride).
- The other ingredients in the tablet core are: magnesium stearate (E470 B), colloidal anhydrous silica (E551), maltodextrin, maize starch, lactose monohydrate and in the tablet coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b).

What Ivabradine Tablets look like and contents of the pack

Ivabradine 5mg Film-coated Tablets are white or almost white, oval, biconvex, Film-coated tablet, marked with "A274" on one side and score on the other side, tablet dimensions 8.2 x 4.1mm.

Ivabradine 7.5mg Film-coated Tablets are white or almost white, triangular, biconvex, Film-coated tablet, marked with "A267" on one side, tablet dimensions 7.5 x 7.2mm.

OPA-Aluminium-PE-Desiccant/Aluminium-PE blister packs. The desiccant is embedded in a polyolefin sealant layer. Multi-layered foil does not allow contact between desiccant and tablets. The blisters are packed in cardboard boxes containing: 56 film-coated tablets.

Marketing Authorisation Holder

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Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.