

ABRAD Film Coated Tablets

Ivabradine (5 mg, 7.5 mg)

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What ABRAD is used for

ABRAD contains the active substance 'ivabradine'. It 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.

Stable angina pectoris:

Usually referred to as angina, it is a heart disease which happens when the heart does not receive enough oxygen. It usually appears between 40 and 50 years of age. The most common symptom of angina is chest pain or discomfort. Angina is more likely to happen when the heart beats faster in situations such as exercise, emotion, exposure to the cold or after eating. This increase in heart rate can cause chest pain in people who suffer from angina.

Chronic heart failure:

It 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 ABRAD works

ABRAD mainly works by reducing the heart rate by a few beats per minute. This lowers the heart's need for oxygen especially in the situations when an angina attack is more likely to happen. In this way ABRAD helps to control and reduce the number of angina attacks. Furthermore, as elevated heart rate adversely affects the heart functioning in patients with chronic heart failure, the specific heart rate lowering action of ivabradine helps to improve the heart functioning in these patients.

Before you use ABRAD

- When you must not use it

Do not take ABRAD if:

- you are allergic to ivabradine or any other ingredients in this medicine
- your resting heart rate is too slow before treatment (below 70 beats per minute)
- you suffer from cardiogenic shock (a heart condition treated in hospital)
- you suffer from a heart rhythm disorder
- you are having a heart attack
- you suffer from very low blood pressure
- you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion)
- you have heart failure which has recently become worse
- your heartbeat is exclusively imposed by your pacemaker
- you suffer from severe liver problems
- you are taking medicines for fungal infection (such as ketoconazole, itraconazole), macrolide antibiotics (such as josamycin, clarithromycin, telithromycin, or erythromycin given orally), medicines for HIV infection (such as nelfinavir, ritonavir), medicines for high blood pressure or angina pectoris

(such as diltiazem, verapamil), or nefazodone (used for depression)

- you are a woman able to have children and not using reliable contraception
- you are pregnant or trying to become pregnant
- you are breast-feeding

Pregnancy and breast-feeding

Do not take ABRAD if you are pregnant or planning to get pregnant.

Do not take ABRAD if you are able to become pregnant unless you use a reliable contraceptive measure.

Do not take ABRAD if you are breast-feeding, talk to your doctor if you plan to breast-feed.

- Before you start to use it

Talk to your doctor or pharmacist before taking ABRAD 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'
- have symptoms such as tiredness, dizziness or shortness of breath (this could mean that your heart is slowing down too much)
- have had a stroke recently (cerebral attack)
- have mild to moderate low blood pressure
- suffer from uncontrolled blood pressure, especially after changing your antihypertensive treatment
- have severe heart failure or heart failure with abnormality of ECG called 'bundle branch block'
- have chronic eye retinal disease
- have moderate liver problem
- have severe renal problem

ABRAD is not intended for use in children and adolescents younger than 18 years.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes herbal medicine that obtained without a prescription.

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In particular, tell your doctor if you are taking any of the following medicines:

- fluconazole (for fungal infection)
- rifampicin (for bacterial infection)
- barbiturates (for difficult sleeping or epilepsy)
- phenytoin (for epilepsy)
- *Hypericum perforatum* or St John's Wort (herbal treatment for depression)
- QT prolonging medicine to treat either heart rhythm disorders or other conditions:
 - quinidine, disopyramide, ibutilide, sotalol, amiodarone (for heart rhythm disorder)
 - bepridil (for angina pectoris)
 - pimozide, ziprasidone, sertindole (to treat anxiety, schizophrenia or other psychoses)
 - mefloquine or halofantrine (for malarial infection)
 - intravenous erythromycin (antibiotic given by injection)
 - pentamidine (for parasitic infection)
 - cisapride (for gastro-oesophageal reflux)
 - diuretics such as furosemide, hydrochlorothiazide, indapamide which may decrease the potassium level in blood (for oedema, high blood pressure)

How to use ABRAD

- How much to use

Stable angina pectoris:

The starting dose should not exceed one tablet of ABRAD 5 mg twice daily. If you still have angina symptoms and tolerated the 5 mg twice daily dose well, the dose may be increased. The maintenance dose should not exceed 7.5 mg twice daily.

Chronic heart failure:

The usual recommended starting dose is one tablet of ABRAD 5 mg twice daily and increase to one tablet of ABRAD 7.5 mg twice daily, if necessary.

Your doctor will decide the right dose for you. The usual dose is one

tablet in the morning and one tablet in the evening. If you are elderly, your doctor may prescribe half the dose [i.e. one half 5 mg tablet of ABRAD (corresponding to 2.5 mg ivabradine) in the morning and one half 5 mg tablet in the evening].

- When to use it

ABRAD should be taken during meals.

- How long to use it

Continue taking ABRAD for as long as your doctor recommends.

- If you forget to use it

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

- If you use too much (overdose)

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

- If you stop using ABRAD

- As the treatment for angina or chronic heart failure is usually life-long, you should discuss with your doctor before stopping ABRAD
- Talk to your doctor if you think that the effect of ABRAD is too strong or too weak
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist

While you are using ABRAD

- Things you must do

- Take your medicine exactly as your doctor has told you
- Tell all the doctors, dentists and pharmacists treating you that you are taking ABRAD
- Tell your doctor immediately if you become pregnant while taking this medication

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor
- Do not take any new medicines without consulting your doctor

- Do not give ABRAD to anyone else, even if they have the same symptoms or condition as you

- Things to be careful of

ABRAD with food and drink

Avoid grapefruit juice during treatment with ABRAD.

Driving and using machines

ABRAD may cause temporary luminous phenomena (phosphenes). 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.

ABRAD contains lactose

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

Side effects

ABRAD can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention: very common (may affect more than 1 in 10 people); common (may affect up to 1 in 10 people); uncommon (may affect up to 1 in 100 people); rare (may affect up to 1 in 1,000 people); very rare (may affect up to 1 in 10,000 people); not known (frequency cannot be estimated from available data).

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

Very common

Luminous phenomena (phosphenes), a temporary visual symptom which causes some patients see bright spots of light, a halo, coloured flashes or distorted images. This phenomenon is most often caused by sudden changes in light intensity, particularly when moving between dim and bright lighting conditions. They generally occur within the first two months of treatment after which they may occur repeatedly and resolve during or after treatment.

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Common

Bradycardia (slowing down of heart rate) particularly occur within the first 2 to 3 months of treatment initiation.

Other side effects have also been reported:

Common

Rapid and irregular heartbeat, abnormal perception of heartbeat, uncontrolled blood pressure, headache, dizziness and blurred vision.

Uncommon

Palpitations and cardiac extra beats, feeling sick (nausea), constipation, diarrhoea, abdominal pain, spinning sensation (vertigo), difficulty breathing (dyspnoea), muscle cramps, changes in laboratory parameters: 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), skin rash, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), low blood pressure, fainting, feeling of tiredness, feeling of weakness, abnormal ECG heart tracing.

Rare

Urticaria, itching, skin reddening, feeling unwell.

Very rare

Irregular heartbeats.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ABRAD

Storage

Keep this medicine out of the sight and reach of children.
Store below 30°C in the original package to protect from moisture.

Disposal

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 protect the environment.

Product Description

- What it looks like

ABRAD is provided in packs. Each pack contains 4 blisters, each blister has 14 tablets. This gives a total of 56 tablets per pack.

ABRAD 5 mg:

White colored, oval shape, biconvex, film coated tablet scored and engraved with '5' at one side, plain on the other with nominal dimensions of 8.6 mm length, 4.5 mm width and 3.1 mm thickness.

ABRAD 7.5 mg:

White colored, round, biconvex, film coated tablet, engraved with '7.5' at one side, plain on the other with a nominal diameter of 6.3 mm and nominal thickness of 4.3 mm.

- Ingredients

- Active ingredient:

Ivabradine (as hydrochloride)

ABRAD 5 mg: one film-coated tablet contains 5 mg ivabradine (equivalent to 5.390 mg ivabradine hydrochloride)

ABRAD 7.5 mg: one film-coated tablet contains 7.5 mg ivabradine (equivalent to 8.085 mg ivabradine hydrochloride)

- Inactive ingredients:

Tablet content:

Cellulose microcrystalline, Lactose monohydrate, Croscarmellose sodium, Silica colloidal anhydrous, Magnesium stearate

Tablet coating:

Hypromellose, Titanium dioxide, Macrogol 6000, Magnesium stearate, Glycerol

MAL number

MAL25036166ACZ (5 mg)

MAL25036167ACZ (7.5 mg)

Manufacturer

Genepfarm S.A.
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Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd.

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