

BRAVIGO Film Coated Tablet

Ivabradine (5mg & 7.5mg)

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What BRAVIGO is used for

BRAVIGO (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. It usually appears between 40 and 50 years of age. The most common symptom of angina is chest pain or discomfort. Angina is most likely to happen when the heart beats faster in situations such as exercise, emotion, exposure to the cold or after eating. The increase in heart rate can cause the chest pain in people who suffer from angina.

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 BRAVIGO works

BRAVIGO 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 BRAVIGO helps to control and reduce the number of angina attacks.

Furthermore, as elevated heart rate adversely affects the heart functioning and vital prognosis in patients with chronic heart failure, the specific heart rate lowering action of ivabradine helps to improve the heart functioning and vital prognosis in these patients.

Before you use BRAVIGO

When you must not use it

Do not take BRAVIGO

- if you are allergic to ivabradine or any of the other ingredients of this medicine;
- 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 suffer from a heart rhythm disorder;
- if you are having a heart attack;
- if you suffer from very low blood pressure;
- if you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion);
- if you have heart failure which has recently become worse;
- if your heartbeat is exclusively imposed by your pacemaker;
- if you suffer from severe liver problems;
- if you are already taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as josamycin, clarithromycin, 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.

Pregnancy and breast feeding

Do not take BRAVIGO if you are pregnant or are planning to have a baby (see "Do not take BRAVIGO").

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

Do not take BRAVIGO if you are able to become pregnant unless you use reliable contraceptive measures (see "Do not take BRAVIGO").

Do not take BRAVIGO if you are breast-feeding (see "Do not take BRAVIGO"). Talk to your doctor if you are breast-feeding or intending to breast-feed as breastfeeding should be discontinued if you take BRAVIGO.

Before you start to use it

Talk to your doctor or pharmacist before taking BRAVIGO

- 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 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,

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- if you suffer from severe renal problems.

If any of the above applies to you, talk straight away to your doctor before or while taking BRAVIGO.

Children

BRAVIGO 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, 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 BRAVIGO or monitoring should be required:

- 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)
- QT prolonging medicines to treat either heart rhythm disorders or other conditions:
- quinidine, disopyramide, ibutilide, sotalol, 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);
- intravenous erythromycin (an antibiotic);
- pentamidine (an antiparasitic medicine);
- cisapride (against the gastro-oesophageal reflux);
- Some types of diuretics which may cause decrease in blood potassium level, such as furosemide, hydrochlorothiazide, indapamide (used to treat oedema, high blood pressure).

How to use BRAVIGO

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

How much to use

If you are being treated for stable angina pectoris:

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

If you are being treated for chronic heart failure

The usual recommended starting dose is one tablet of BRAVIGO 5 mg twice daily increasing if necessary to one tablet of BRAVIGO 7.5 mg 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 elderly), your doctor may prescribe half the dose i.e., one half 5 mg tablet of BRAVIGO 5 mg (corresponding to 2.5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

When to use it

BRAVIGO should be taken during meals.

How long to use it

Continue taking BRAVIGO for as long as your doctor recommends.

If you forget to use it

If you forget to take a dose of BRAVIGO, 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 BRAVIGO could make you feel breathless or tired because your heart slows down too much. If this happens, contact your doctor immediately.

If you stop taking BRAVIGO

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 BRAVIGO 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.

While you are using it

Thing 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 BRAVIGO.

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 BRAVIGO to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Taking BRAVIGO with food and drink

Avoid grapefruit juice during treatment with BRAVIGO.

Driving and using machines

BRAVIGO 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.

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BRAVIGO 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

Like all medicines, this medicine 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 the 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 symptoms which cause some patients see bright spots of light, a halo, coloured flashes or distorted images. This phenomena 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.

Common:

Bradycardia (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:

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.

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 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 BRAVIGO

Storage

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

Store at temperature below 30°C in the original package to protect from light.

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

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 to protect the environment.

Product Description

What it looks like

BRAVIGO 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.

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

The tablets are available in (Aluminium/aluminium blisters) of 56 tablets. Each carton box contains 4 blisters of 14 tablets each.

Ingredients

Active ingredient

The active substance is ivabradine (as hydrochloride).

BRAVIGO 5 mg: one film-coated tablet contains 5 mg ivabradine (equivalent to 5.39 mg ivabradine as hydrochloride).

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

Inactive ingredients

Tablet core

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

Coating

Hypromellose 6cp (E464)
Titanium dioxide (E171)
Macrogol 6000 (E1521)
Magnesium stearate (E470b)
Glycerol (E422)

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MAL number:

BRAVIGO 5mg: MAL*****

BRAVIGO 7.5mg: MAL*****

Manufacturer

GENEPHARM S.A.
18th Km Marathonos Avenue,
Pallini, 15351, Greece

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22, Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia

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