

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd.**

Product proprietary name: **BRADHET 5 & 7,5**

Dosage form and strength: **Film coated tablet and 5 mg & 7,5 mg**

PATIENT INFORMATION LEAFLET FOR BRADHET 5 & 7,5

SCHEDULING STATUS:

S3

BRADHET 5 film coated tablet

BRADHET 7,5 film coated tablet

Ivabradine hydrochloride

Contains sugar (lactose monohydrate)

BRADHET 5: Contains 72,610 mg lactose monohydrate.

BRADHET 7,5: Contains 69,915 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking BRADHET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **BRADHET** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **BRADHET** is and what it is used for
2. What you need to know before you take **BRADHET**
3. How to take **BRADHET**
4. Possible side effects
5. How to store **BRADHET**
6. Contents of the pack and other information

1. What BRADHET is and what it is used for

BRADHET is a medicine used to treat:

- Symptomatic treatment in of stable chronic angina pectoris, 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, or 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 too high (over or equal to 77 beats per minute. It is used in combination with standard therapy, including beta-blockers 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 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 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.
- **BRADHET** mainly works by reducing your heart rate. This lowers the heart's need for oxygen. This lowers the heart's need for oxygen especially in the situations when an angina attack is more likely to happen. In this way **BRADHET** helps to control and reduce the number of angina attacks.

2. What you need to know before you take BRADHET

Do not take BRADHET:

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- If you are hypersensitive (allergic) to ivabradine hydrochloride or any of the other ingredients of **BRADHET** (listed in section 6).
- If you are a woman able to have children and not using appropriate contraception with proven efficacy.
- If you are pregnant or trying to become pregnant.
- If you are breastfeeding.
- If your heartbeat is exclusively imposed by your pacemaker.
- If your resting heart rate before treatment is too slow (below 70 beats per minute).
- If you suffer from very low blood pressure.
- If you are suffering from cardiogenic shock (a heart condition treated in hospital).
- If you have heart failure which has recently become worse, or heart failure with abnormality of ECG called bundle branch block.
- If you are having a heart attack.
- If you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion).
- Congenital (inborn) long QT syndrome on your ECG.
- If you are taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as azithromycin, clarithromycin, telithromycin or erythromycin given orally), medicines to treat HIV infections (such as nelfinavir, ritonavir).
- If you are taking diltiazem, verapamil (used for high blood pressure or angina pectoris).
- If you are taking St. John's Wort.
- If you suffer from severe liver problems.
- If you suffer from a heart rhythm disorder.
- If you are taking QT-prolonging medicines to treat either heart rhythm disorders or other conditions.

Warnings and precautions

Take special care with BRADHET:

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- 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 or shortness of breath (this could mean 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 suffer from severe heart failure or heart failure with abnormality of ECG called bundle branch block.
- 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 chronic eye retinal disease (visual problems related to disease of the retina).
- If you suffer from liver problems.
- If you suffer from severe renal problems.
- If you have abnormal heart valves.

If any of the above applies to you, talk to your doctor before or while taking **BRADHET**.

Children and adolescents

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

Other medicines and BRADHET

Always tell your health care provider if you are taking any other medicine. (This included all complementary or traditional medicines).

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

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Do not take BRADHET with the following medicines (see Do not take BRADHET):

- Antifungals (ketoconazole, itraconazole), antibiotics (ciclosporin, gestodene, clarithromycin, erythromycin, josamycin, telithromycin), HIV medicine (nelfinavir, ritonavir) and nefazodone
- Diltiazem and verapamil – to treat chest pain (angina) and prevent strokes, heart attacks and kidney problems, as the effect of BRADHET may be increased

Taking the following with BRADHET is not recommended:

- Grapefruit juice, as this may enhance the effect of BRADHET
- Heart medicines, such as quinidine, disopramide, bepridil, sotalol and ibutilide, may affect the way BRADHET works (see Do not take BRADHET)
- Antidepressants, medicines for mental disorders, such as pimozide, ziprasidone, sertindole, mefloquine and halofantrine (used to treat malaria), pentamidine (to treat fungal infections), cisapride (to treat acid reflux) and erythromycin IV (antibiotic).

Taking the following medicines with BRADHET must be done with caution:

- Fluconazole (used in the treatment of yeast infections)
- Rifampicin (antibiotic), sedatives called barbiturates, phenytoin (to treat epilepsy) and St John's Wort (a medicinal plant), as this may affect the dose of BRADHET
- Water tablets (called thiazide diuretics and loop diuretics) may increase the risk of reduced potassium levels in your blood and abnormal heartbeat.

BRADHET with food and drink

Do not take grapefruit juice during treatment with **BRADHET**.

Pregnancy, breastfeeding and fertility

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Do not take BRADHET if you are pregnant and/or breastfeeding, as BRADHET has shown to be cause deformities in animal reproductive studies.

You should not take **BRADHET** if you are pregnant or breastfeeding.

Should you become a pregnant while using **BRADHET** you must immediately stop taking it and consult your doctor without delay.

Do not take **BRADHET** if you are able to become pregnant unless you use appropriate contraception with proven efficacy.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice, before taking **BRADHET**.

Driving and using machines

BRADHET may cause temporary visual disturbances and dizziness. If this happens to you be careful when driving vehicles or operating machines, particularly at times when there could be sudden changes in light intensity.

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

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **BRADHET**.

3. How to take BRADHET

Do not share medicines prescribed for you with any other person.

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

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If you are being treated for stable angina pectoris:

The starting dose should not exceed one tablet of **BRADHET** 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. 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 elderly), your doctor may prescribe half the dose i.e. one half 5 mg tablet of **BRADHET** 5 mg (corresponding to 2,5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

If you are being treated for chronic heart failure:

The starting dose is one tablet of **BRADHET** 5 mg twice daily increasing if necessary to one tablet of **BRADHET** 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 **BRADHET** 5 mg (corresponding to 2,5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

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

Method of administration:

BRADHET should be taken with food.

Swallow your tablet(s) with a glass of water, in the morning and in the evening.

If you take more BRADHET than you should

A large dose of **BRADHET** could make you feel dizzy, breathless or tired because your heart rate slows down too much, and your blood pressure decreases.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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If you forget to take BRADHET

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **BRADHET** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking BRADHET

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

If you think that the effect of **BRADHET** 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

BRADHET can have side effects.

Not all side effects reported for **BRADHET** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BRADHET**, please consult your health care provider for advice.

If any of the following happens, stop taking BRADHET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to **BRADHET**. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- low heart rate making you feel dizzy, tired or lightheaded
- irregular rapid contraction of the heart, abnormal perception of heartbeat, palpitations
- Increased (high) or decreased (low) blood pressure
- blurred vision, distortion of light (brief moments of increased brightness, most often caused by sudden changes in light intensity)
- breathing problems (dyspnoea)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Dizziness, may be due to slow heartbeat
- Fainting, may be due to slow heartbeat
- 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.
- Blurred vision (cloudy vision)
- Slow heartbeat
- Irregular rapid contraction of the heart
- Abnormal perception of heartbeat
- High blood pressure

Less frequent:

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- Increase of eosinophils (a type of white blood cell)
- High blood levels of uric acid
- Palpitations and cardiac extra beats
- Difficulty breathing
- High levels of creatinine in blood (a breakdown product of muscle)
- Abnormal ECG heart tracing

Frequency unknown:

- Double vision
- Irregular heartbeats
- Low blood pressure, may be due to slow heartbeat
- Redness and inflammation of the skin
- Unusual tiredness and weakness, may be due to slow heartbeat
- Feeling unwell, may be due to slow heartbeat

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Headache (particularly occurs during the first month of treatment)
- Nausea (feeling sick)
- Constipation
- Diarrhoea

Less frequent:

- Muscle cramps

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Frequency unknown:

- Stomach pain
- Rash
- Itching

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za>. or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **BRADHET**.

5. How to store BRADHET

- Store at 25 °C, excursions permitted to 15 °C to 30 °C (59 °F – 89 °F).
- Protect from light and moisture.
- Store the tablets in the original container until required for use.
- Store all medicines out of reach of children.
- There are no special storage instructions for **BRADHET**.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BRADHET contains

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- The active substance is ivabradine hydrochloride.
- The other ingredients are corn starch, colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maltodextrin, purified water
- Opadry tan 03G580014 (consists of HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG, glycerin, magnesium stearate)
- Opadry tan 03G570019 (consists of HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG, glycerin, magnesium stearate, iron oxide yellow, ferrosoferric oxide NF/black iron oxide, iron oxide red)

What BRADHET looks like and contents of the pack

BRADHET 5: White to off white-colored, oval shaped, film-coated tablet, scored on both edges, debossed with "V" on the one side and "9" bisected "1" on other side.

BRADHET 7,5: Tan colored oval shaped, film-coated tablet, debossed with "V" on the one side and "92" on other side.

Contents of the pack

HDPE bottle:

Tablets are pack in a white opaque high density polyethylene container (HDPE) container with white opaque polypropylene child resistant closure with pulp liner containing 2,0 g silica gel canister as a desiccant.

Pack size: 60's and 180's

Blister strips:

Blister strips of cold form pack film with desiccant as a forming film and plain aluminium form pack film with desiccant as a lidding foil, containing 10 tablets per blister.

Pack sizes: 10 tablets per blister. 10's x 10 blisters packed in a box.

HDPE bottle and blister strips are enclosed in an outer carton box.

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Not all pack sizes may be marketed.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd.

Waterfall Corporate Campus,

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Midrand,

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This leaflet was last revised in

N/A

Registration number(s)

BRADHET 5: 57/7.1.4/0277.

BRADHET 7,5: 57/7.1.4/0278.

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd.

Waterfall Corporate Campus

Building No. 2, First floor

74 Waterfall Drive

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