Package leaflet: information for the patient

Brediwal® 5 mg, filmomhulde tabletten
Brediwal® 7,5 mg, filmomhulde tabletten

ivabradine

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.

What is in this leaflet:

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] (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 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.

How does [Nationally completed name] work?
[Nationally completed name] 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 [Nationally completed name] 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.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- 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 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 heart beat 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name]
- 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 straight away to your doctor before or while taking [Nationally completed name].

Children and adolescents
[Nationally completed name] is not intended for use in children and adolescents younger than 18 years.

Other medicines and [Nationally completed name]
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 [Nationally completed name] 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).

[Nationally completed name] with food and drink
Avoid grapefruit juice during treatment with [Nationally completed name].

Pregnancy and breast-feeding
Do not take [Nationally completed name] if you are pregnant or are planning to have a baby (see "Do not take [Nationally completed name]").
If you are pregnant and have taken [Nationally completed name], talk to your doctor.
Do not take [Nationally completed name] if you are able to become pregnant unless you use reliable contraceptive measures (see "Do not take [Nationally completed name]").
Do not take [Nationally completed name] if you are breast-feeding (see "Do not take [Nationally completed name]"). Talk to your doctor if you are breast-feeding or intending to breast-feed as breastfeeding should be discontinued if you take [Nationally completed name].
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.

Driving and using machines
[Nationally completed name] 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.

[Nationally completed name] contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
[Nationally completed name] should be taken during meals.
The tablet of 5 mg strength can be divided into equal doses.

If you are being treated for stable angina pectoris
The starting dose should not exceed one tablet of [Nationally completed name] 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 recommended 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 [Nationally completed name] 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 recommended starting dose is one tablet of [Nationally completed name] 5 mg twice daily increasing if necessary to one tablet of [Nationally completed name] 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 [Nationally completed name] 5 mg (corresponding to 2.5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

If you take more [Nationally completed name] than you should:
A large dose of [Nationally completed name] 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 [Nationally completed name]:
If you forget to take a dose of [Nationally completed name], take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

[For calendar blister packs]The calendar printed on the blister containing the tablets should help you remember when you last took a tablet of [Nationally completed name].

If you stop taking [Nationally completed name]:
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 [Nationally completed name] 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.

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):
Irregular rapid contraction of the heart, abnormal perception of heartbeat, uncontrolled blood pressure, headache, dizziness and blurred vision (cloudy vision).

Uncommon (may affect up to 1 in 100 people):
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, double vision, impaired vision.

Rare (may affect up to 1 in 1,000 people):
Urticaria, itching, skin reddening, feeling unwell.

Very rare (may affect up to 1 in 10, 000 people):
Irregular heart beats.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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, the bottle 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 use the medicine packed in bottles longer than 6 months after first opening.

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. Content of the pack and other information

What [Nationally completed name] contains
- The active substance is ivabradine. Each film-coated tablet contains 5 mg of ivabradine (as oxalate).
  Each film-coated tablet contains 7.5 mg of ivabradine (as oxalate).

- The other ingredients are lactose anhydrous, colloidal anhydrous silica, croscarmellose sodium (E 468); butylhydroxytoluene (E 321), magnesium stearate (E 470b) in the tablet core and hypromellose (E 464), titanium dioxide (E 171), macrogol 6000, glycerol (E 422), magnesium stearate (E 470b), yellow iron oxide (E 172), red iron oxide (E 172) in the film-coating.

What [[Nationally completed name] looks like and contents of the pack

5 mg film-coated tablets:
Yellow coloured, round (6.0 mm), film-coated tablets debossed with ´5´ on one side and scored on other side.
The tablet can be divided into equal doses.

7.5 mg film-coated tablets:
Orange-yellow coloured, round (6.5 mm), biconvex, film-coated tablets debossed with ´7.5´ on one side.

The tablets are packed in OPA/Aluminium/PVC/Aluminium or PVC/PE/PVDC /Aluminium blisters or are packed in a HDPE bottle with PP child resistant screw cap containing desiccant (silica gel) and inserted in a carton, or are packed in a HDPE bottle with PP child resistant screw cap containing desiccant (silica gel).

Pack sizes:
NL/H/3640+3784:
Blister: 10, 14, 28, 30, 56, 60, 84, 90, 98, 100, 112 film-coated tablets
Calendar blister pack: 14, 28, 30, 56, 60, 84, 100, 112 film-coated tablets
Bottle: 100, 250 film-coated tablets

NL/H/3641:
Blisters: 10, 14, 28, 30, 56, 60, 84, 98, 100, 112 film-coated tablets
Calendar blister pack: 28, 30, 56, 60, 98 film-coated tablets
Bottle: 100 film-coated tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

HBM Pharma s.r.o
Sklabinská 30, Martin
036 80
Slowakije

Delorbis Pharmaceuticals Limited
17 Athinon Street,
Ergates Industrial Area,
2643 Ergates, Lefkosia
Cyprus

In het register ingeschreven onder:
Brediwal 5 mg, filmomhulde tabletten - RVG 119250.
Brediwal 7,5 mg, filmomhulde tabletten - RVG 119251.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Brediwal 5 mg, filmomhulde tabletten
	Brediwal 7,5 mg, filmomhulde tabletten
Polen	Brediwal
Bulgarije	Brediwal
Letland	Brediwal 5 mg apvalkotās tabletes
	Brediwal 7,5 mg apvalkotās tabletes
Litouwen	Brediwal 5 mg plėvele dengtos tabletės
	Brediwal 7,5 mg plėvele dengtos tabletės
Estland	Brediwal
Slovenië	Brediwal

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2021