

Package leaflet: Information for the user

Bosutinib Newbury 100 mg filmomhulde tabletten
Bosutinib Newbury 400 mg filmomhulde tabletten
Bosutinib Newbury 500 mg filmomhulde tabletten

bosutinib

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What [Product Name] is and what it is used for

[Product Name] contains the active substance bosutinib. It is used to treat adult patients who have a type of leukaemia called Philadelphia chromosome-positive (Ph-positive) Chronic Myeloid Leukaemia (CML) and are newly-diagnosed or for whom previous medicines to treat CML have either not worked or are not suitable. Ph-positive CML is a cancer of the blood which makes the body produce too many of a specific type of white blood cell called granulocytes.

If you have any questions about how [Product Name] works or why this medicine has been prescribed for you, ask your doctor.

2. What do you need to know before you take [Product Name]

Do not take [Product Name]

- if you are allergic to bosutinib or any of the other ingredients of this medicine (listed in section 6).
- if your doctor has told you that your liver has been damaged and is not working normally.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Product Name]:

- **if you have, or have had in the past, liver problems.** Tell your doctor if you have a history of liver problems including hepatitis (liver infection or inflammation) of any kind, or a history of any of the following signs and symptoms of liver problems: itching, yellow eyes or skin, dark urine, and pain or discomfort in the right upper stomach area. Your doctor should do blood tests to check your liver function prior to your starting treatment with [Product Name] and for the first 3 months of treatment with [Product Name], and as clinically indicated.
- **if you have diarrhoea and vomiting.** Tell your doctor if you develop any of the following signs and symptoms: an increase in the number of stools (bowel movements) per day over

normal, an increase in episodes of vomiting, blood in your vomit, stools (bowel movements) or urine, or have black stools (tarry black bowel movements). You should ask your doctor if use of your treatment for vomiting may result in a greater risk of heart arrhythmias. In particular, you should ask your doctor if you want to use a medicine containing domperidone for the treatment of nausea and/or vomiting. Treatment of nausea or vomiting with such medicines together with [Product Name] may result in a greater risk of dangerous heart arrhythmias.

- **if you suffer from bleeding problems.** Tell your doctor if you develop any of the following signs and symptoms such as abnormal bleeding or bruising without having an injury.
- **if you have an infection.** Tell your doctor if you develop any of the following signs and symptoms such as fever, problems with urine such as burning on urination, a new cough, or a new sore throat.
- **if you have fluid retention.** Tell your doctor if you develop any of the following signs and symptoms of fluid retention during [Product Name] treatment such as swelling of the ankles, feet or legs; difficulty breathing chest pain or a cough (these may be signs of fluid retention in the lungs or chest).
- **if you have heart problems.** Tell your doctor if you have a heart disorder, such as heart failure and decreased blood flow to the heart which can lead to heart attack. Get medical help right away if you get shortness of breath, weight gain, chest pain or swelling in your hands, ankles or feet.
- **if you have been told you have an abnormal heart rhythm.** Tell your doctor if you have arrhythmias or an abnormal electrical signal called “prolongation of the QT interval”. This is always important, but especially if you are experiencing frequent or prolonged diarrhoea as described above. If you faint (loss of consciousness) or have an irregular heartbeat while taking [Product Name], tell your doctor immediately, as this may be a sign of a serious heart condition.
- **if you have been told that you have problems with your kidneys.** Tell your doctor if you are urinating more frequently and producing larger amounts of urine with a pale colour or if you are urinating less frequently and producing smaller amounts of urine with a dark colour. Also tell your doctor if you are losing weight or have experienced swelling of your feet, ankles, legs, hands or face.
- **if you have ever had or might now have a hepatitis B infection.** This is because [Product Name] could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- **if you have or have had pancreas problems.** Tell your doctor if you develop abdominal pain or discomfort.
- **if you have any of these symptoms: serious skin rashes.** Tell your doctor if you develop any of the following signs and symptoms of painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (such as mouth and lips).
- **if you notice any of these symptoms: pain in your side, blood in your urine or reduced amount of urine.** When your disease is very severe, your body may not be able to clear all the waste products from the dying cancer cells. This is called tumour lysis syndrome and can cause kidney failure and heart problems within 48 hours of the first dose of [Product Name]. Your doctor will be aware of this and may ensure you are adequately hydrated and give you other medicines to help prevent it.

Sun/UV protection

You may become more sensitive to the sun or UV rays while taking bosutinib. It is important to cover sunlight-exposed areas of skin and use sunscreen with high sun protection factor (SPF).

Children and adolescents

[Product Name] is not recommended for people whose age is under 18 years. This medicine has not been studied in children and adolescents.

Other medicines and [Product Name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, vitamins, and herbal medicines. Some medicines can affect the levels of [Product Name] in your body. You should inform your doctor if you are taking medicines containing active substances such as those listed below:

The following active substances may increase the risk of side effects with [Product Name]:

- ketoconazole, itraconazole, voriconazole, posaconazole and fluconazole, used to treat fungal infections.
- clarithromycin, telithromycin, erythromycin, and ciprofloxacin, used to treat bacterial infections.
- nefazodone, used to treat depression.
- mibefradil, diltiazem and verapamil, used to lower blood pressure in people with high blood pressure.
- ritonavir, lopinavir/ritonavir, indinavir, nelfinavir, saquinavir, atazanavir, amprenavir, fosamprenavir and darunavir, used to treat human immunodeficiency virus (HIV)/AIDS.
- boceprevir and telaprevir, used to treat hepatitis C.
- aprepitant, used to prevent and control nausea (feeling sick) and vomiting.
- imatinib, used to treat a type of leukaemia.
- crizotinib, used to treat a type of lung cancer called non-small cell lung cancer.

The following active substances may reduce the effectiveness of [Product Name]:

- rifampicin, used to treat tuberculosis.
- phenytoin and carbamazepine, used to treat epilepsy.
- bosentan, used to lower high blood pressure in the lungs (pulmonary artery hypertension).
- nafcillin, an antibiotic used to treat bacterial infections.
- St. John's Wort (a herbal preparation obtained without a prescription), used to treat depression.
- efavirenz and etravirine, used to treat HIV infections/AIDS.
- modafinil, used to treat certain types of sleep disorders.

These medicines should be avoided during your treatment with [Product Name]. If you are taking any of them, tell your doctor. Your doctor may change the dose of these medicines, change the dose of [Product Name], or switch you to a different medicine.

The following active substances may affect the heart rhythm:

- amiodarone, disopyramide, procainamide, quinidine and sotalol used to treat heart disorder.
- chloroquine, halofantrine used to treat malaria.
- clarithromycin and moxifloxacin antibiotics used to treat bacterial infections.
- haloperidol, used to treat psychotic disease such as schizophrenia.
- domperidone, used to treat nausea and vomiting or to stimulate breast milk production.
- methadone, used to treat pain.

These medicines should be taken with caution during your treatment with [Product Name]. If you are taking any of them, tell your doctor.

The medicines listed here may not be the only ones that could interact with [Product Name].

[Product Name] with food and drink

Do not take [Product Name] with grapefruit or grapefruit juice, as it may increase the risk of side effects.

Pregnancy, breast-feeding and fertility

[Product Name] is not to be used during pregnancy, unless clearly necessary, because [Product Name] could harm an unborn baby. Ask your doctor for advice before taking [Product Name] if you are pregnant or might become pregnant.

Women taking [Product Name] will be advised to use effective contraception during treatment and for at least 1 month after the last dose. Vomiting or diarrhoea may reduce the effectiveness of oral contraceptives.

There is a risk that treatment with this medicine will lead to decreased fertility and you may wish to seek advice about sperm storage before the treatment starts.

If you are breast-feeding, tell your doctor. Do not breast-feed during treatment with [Product Name] as it could harm your baby.

Driving and using machines

If you experience dizziness, have blurred vision or feel unusually tired, do not drive or operate machines until these side effects have gone away.

[Product Name] contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg, 400 mg, or 500 mg tablet, that is to say essentially 'sodium-free'.

3. How to take [Product Name]

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

[Product Name] will only be prescribed to you by a doctor with experience in medicines to treat leukaemia.

Dose and method of administration

The recommended dose is 400 mg once daily for patients with newly-diagnosed CML. The recommended dose is 500 mg once daily for patients whose previous medicines to treat CML have either not worked or are not suitable. In the event that you have moderate or severe kidney problems, your doctor will reduce your dose by 100 mg once daily for moderate kidney problems and by an additional 100 mg once daily for severe kidney problems. Your doctor may adjust the dose using the 100 mg tablets depending upon your medical conditions, upon your response to treatment and/or on any side effect you may experience. Take the tablet(s) once a day with food. Swallow the tablet(s) whole with water.

If you take more [Product Name] than you should

If you accidentally take too many [Product Name] tablets or a higher dose than you need, contact a doctor for advice right away. If possible, show the doctor the pack, or this leaflet. You may require medical attention.

If you forget to take [Product Name]

If dose is missed by less than 12 hours, take your recommended dose. If a dose is missed by more than 12 hours, take your next dose at your regular time on the following day. Do not take a double dose to make up for the forgotten tablets.

If you stop taking [Product Name]

Do not stop taking [Product Name] unless your doctor tells you to do so. If you are not able to take the medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor right away.

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.

You must immediately contact your doctor if you experience any of those serious side effects (see also section 2 “**What you need to know before you take [Product Name]**”):

Blood disorders. Tell your doctor right away if you have any of these symptoms: bleeding, fever or easy bruising (you might have blood or lymphatic system disorder).

Liver disorders. Tell your doctor right away if you have any of these symptoms: itching, yellow eyes or skin, dark urine, and pain or discomfort in the right upper stomach area or fever.

Stomach/intestinal disorders. Tell your doctor if you develop stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting.

Heart problems. Tell your doctor if you have a heart disorder, such as heart failure, decreased blood flow to the heart, an abnormal electrical signal called “prolongation of the QT interval”, or if you faint (loss of consciousness) or have an irregular heart beat while taking [Product Name].

Hepatitis B reactivation. Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection).

Severe skin reactions. Tell your doctor right away if you have any of these symptoms: painful red or purplish rash that spreads and blisters and/or other lesions begin to appear in the mucous membrane (such as mouth and lips).

Side effects with [Product Name] may include:

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

- reduction in the number of platelets, red blood cells and/or neutrophils (type of white blood cells).
- diarrhoea, vomiting, stomach pain, nausea.
- fever, swelling of hands, feet or face, fatigue, weakness.
- respiratory tract infection.
- nasopharyngitis.
- changes in blood test to determine if [Product Name] is affecting your liver and/or pancreas, kidneys.
- decrease of appetite.
- joint pain, back pain.
- headache.
- skin rash, which may be itchy and/or generalised.
- cough.
- shortness of breath.
- feeling of instability (dizziness).
- fluid in the lungs (pleural effusion).
- itching.

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

- low white blood cells count (leukopenia).
- stomach irritation (gastritis), bleeding from the stomach or intestine.
- chest pain, pain.
- toxic damage to the liver, abnormal hepatic function including liver disorder.
- infection of the lung (pneumonia), influenza, bronchitis.
- when the heart does not pump blood as well as it should (heart failure).
- defect in cardiac rhythm that predisposes to fainting, dizziness and palpitation.
- increase in blood pressure.
- high level of potassium in the blood, low level of phosphorus in the blood, excessive loss of body fluid (dehydration).
- pain in the muscles.
- alteration of the sense of taste (dysgeusia).
- acute kidney failure, kidney failure, kidney impairment.
- fluid around the heart (pericardial effusion).
- ringing in the ears (tinnitus).
- urticaria (hives), acne.
- photosensitivity reaction (sensitivity to UV rays from the sun and other light sources).
- allergic reaction.
- abnormally high blood pressure in the arteries of the lungs (pulmonary hypertension).
- acute inflammation of the pancreas (acute pancreatitis).
- respiratory failure.

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

- fever associated with low white blood cell count (febrile neutropenia).
- damage to the liver.
- life-threatening allergic reaction (anaphylactic shock).
- abnormal build-up of fluid in the lungs (acute pulmonary oedema).
- skin eruption.
- inflammation of the sac-like covering of the heart (pericarditis).
- a marked decrease in the number of granulocytes (a type of white blood cells).
- severe skin disorder (erythema multiforme).
- nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness associated with abnormal laboratory test results (high potassium, uric acid and phosphorous levels and low calcium levels in the blood) that can lead to changes in kidney function and acute renal failure –(Tumour lysis syndrome (TLS)).
- inflammation of blood vessels in the skin which may result in rash or bruising (cutaneous vasculitis).

Not known (frequency cannot be estimated from the available data):

- severe skin disorder (Stevens-Johnson syndrome, toxic epidermal necrolysis) due to an allergic reaction, exfoliative (scaly, peeling) rash.
- interstitial lung disease (disorders causing scarring in the lungs): signs include cough, difficulty breathing, painful breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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 [Product 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 blister foil, bottle and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

For HDPE bottle pack: Do not remove desiccant.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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.

6. Contents of the pack and other information

What [Product Name] contains

- The active substance is bosutinib. [Product Name] film-coated tablets come in different strengths.
 - [Product Name] 100 mg: each film-coated tablet contains bosutinib monohydrate equivalent to 100 mg bosutinib.
 - [Product Name] 400 mg: each film-coated tablet contains bosutinib monohydrate equivalent to 400 mg bosutinib.
 - [Product Name] 500 mg: each film-coated tablet contains bosutinib monohydrate equivalent to 500 mg bosutinib.
- The other ingredients are:
 - *Tablet core:* cellulose microcrystalline (E460), croscarmellose sodium (E468), poloxamer 188, povidone K25 (E1201), silica, colloidal anhydrous (E551), talc (E553b) and magnesium stearate (E470b).
 - *Film coating:* poly(vinyl alcohol) (E1203), macrogol 3350, titanium dioxide (E171), talc (E553b), iron oxide yellow (E172) and iron oxide red (E172)

What [Product Name] looks like and contents of the pack

Carton box with PVC/PCTFE (ACLAR)– Aluminium blisters

or

60 ml HDPE bottles with child-resistant PP caps and a white cylindrical plastic desiccant canister.

[Product Name] 100 mg film-coated tablets

[Product Name] 100 mg film-coated tablets are light orange to orange, oval (width: approximately 6 mm; length: approximately 11 mm) biconvex, film-coated tablet debossed with “721” on one side and plain on the other side.

Pack size:

[For NL/H/6003/001/DC]

- carton box containing 28, 30 or 112 film-coated tablets in blister pack
- 120 film-coated tablets in bottle pack

[For NL/H/6001/001/DC]

- carton box containing 28 or 112 film-coated tablets in blisters

Not all pack sizes may be marketed.

[For NL/H/6002/001/DC]

- carton box containing 28 film-coated tablets in blisters

[Product Name] 400 mg film-coated tablets

[Product Name] 400 mg film-coated tablets are light orange to orange, oval (width: approximately 9 mm; length: approximately 17 mm) biconvex, film-coated tablet debossed with “722” on one side and plain on the other side.

Pack size:

[For NL/H/6003/002/DC]

- carton box containing 28 or 30 film-coated tablets in blister pack
- 30 film-coated tablets in bottle pack

Not all pack sizes may be marketed.

[For NL/H/6001-6002/002/DC]

- carton box containing 28 film-coated tablets in blister pack

[Product Name] 500 mg film-coated tablets

[Product Name] 500 mg film-coated tablets are light red to red, oval (width: approximately 9 mm; length: approximately 18 mm) biconvex, film-coated tablet debossed with “723” on one side and plain on the other side.

Pack size:

[For NL/H/6003/003/DC]

- carton box containing 28 or 30 film-coated tablets in blister pack
- 30 film-coated tablets in bottle pack

Not all pack sizes may be marketed.

[For NL/H/6001-6002/003/DC]

- carton box containing 28 film-coated tablets in blister pack

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

Houder van de vergunning voor het in de handel brengen

Newbury Pharmaceuticals AB,
Medicon Village, 223 81 Lund,
Zweden

Fabrikanten

Pharmadox Healthcare Limited
Kw20a Kordin Industrial Park
PLA 3000 Paola
Malta

Adalvo Limited
Malta Life Sciences Park Building 1 Level 4
Sir Temi Zammit Buildings
San Gwann Industrial Estate
SGN 3000 San Gwann
Malta

Qualimetrix S.A.
Mesogeion Avenue 579
Agia Paraskevi
153 43 Athene
Griekenland

In het register ingeschreven onder:

Bosutinib Newbury 100 mg filmomhulde tabletten - RVG 132562
Bosutinib Newbury 400 mg filmomhulde tabletten - RVG 132563
Bosutinib Newbury 500 mg filmomhulde tabletten - RVG 132564

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland Bosutinib Newbury 100 mg filmomhulde tabletten

	Bosutinib Newbury 400 mg filmomhulde tabletten
	Bosutinib Newbury 500 mg filmomhulde tabletten
Denemarken	Bosutinib Newbury
Noorwegen	Bosutinib Newbury
Zweden	Bosutinib Newbury 100 mg filmdragerade tabletter
	Bosutinib Newbury 400 mg filmdragerade tabletter
	Bosutinib Newbury 500 mg filmdragerade tabletter

Deze bijsluiter is voor het laatst goedgekeurd in februari 2026