NOVARTIS

BACRELBA

(asciminib hydrochloride)

20 and 40 mg film-coated tablets

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

BACRELBA 20 mg film-coated tablets

BACRELBA 40 mg film-coated tablets

Contains sugar: lactose

BACRELBA 20 mg contains 43,11 mg of lactose per film-coated tablet.

BACRELBA 40 mg contains 86,22 mg of lactose per film-coated tablet.

Read all of this leaflet carefully before you start taking BACRELBA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- BACRELBA 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 BACRELBA is and what it is used for

2. What you need to know before you use BACRELBA

3. How to take BACRELBA

4. Possible side effects

5. How to store BACRELBA

6. Contents of the pack and other information

1. What BACRELBA is

BACRELBA 20 mg or 40 mg film-coated tablets contain the active substance asciminib, which belongs to a group of medicines called protein kinase inhibitors.

What BACRELBA is used for

BACRELBA is used to treat adults with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) who:

- Are newly diagnosed or were previously treated with medicines of a similar type called tyrosine kinase inhibitors.
- Have developed a certain genetic difference (mutation) called T315I.

Ph+ CML is a type of blood cancer (leukaemia) in which the body produces too many abnormal white blood cells. CP is the first phase of this blood cancer.

2. What you need to know before you use BACRELBA

Follow all of your doctor's instructions carefully.

Do not use BACRELBA

- If you are allergic to asciminib or any of the other ingredients of this medicine (listed in section 6).
- If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

If any of these apply to you, tell your doctor, pharmacist, or health care provider before taking BACRELBA:

- If you have or have ever had severe upper stomach pain (inflamed pancreas, pancreatitis).
- If you have or have ever had a hepatitis B infection. This is because during treatment with BACRELBA, hepatitis B may become active again. Patients will be carefully checked by their doctor for signs of this infection before starting treatment.

Tell your doctor or pharmacist or health care provider immediately if you get any of these symptoms during treatment with BACRELBA:

- If you experience weakness, spontaneous bleeding or bruising and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of decreased bone marrow activity, resulting in a reduced number of white blood cells, red blood cells and platelets, myelosuppression).
- If blood tests show that you have high levels of enzymes called lipase and amylase (signs of damage to the pancreas, pancreatic toxicity).
- If you have a heart disorder or a heart rhythm disorder, such as an irregular heartbeat or an abnormal electrical signal called prolongation of the QT interval.
- If blood tests show that you have low levels of potassium or magnesium (hypokalaemia or hypomagnesaemia).
- If you are being treated with medicines that may have an unwanted effect on the function of the heart (torsades de pointes) (see “Taking other medicines”).
- If you experience headache, dizziness, chest pain or shortness of breath (signs of high blood pressure, hypertension).
- If you experience rash, itching, hives, breathlessness or difficulty breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, low blood pressure, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin (signs of allergic reaction).

Monitoring during your treatment with BACRELBA

Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

You will have regular tests including blood tests during treatment. These tests will monitor:

- The amount of blood cells (white blood cells, red blood cells and platelets).
- The levels of pancreas enzymes (amylase and lipase).
- The levels of electrolytes (potassium, magnesium).
- Your heart rate and your blood pressure.

If you have any questions about how BACRELBA works or why it has been prescribed for you, ask your doctor.

Children and adolescents (below 18 years)

BACRELBA is not to be used in children or adolescents under 18 years of age. It is not known whether BACRELBA is safe and effective in children or adolescents.

Elderly people (65 years of age or above)

You can use BACRELBA if you are aged 65 years or over at the same dose as for other adults.

Taking other medicines (interactions with other medicines)

Before you take BACRELBA tell your doctor, pharmacist or health care provider if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, vitamins or herbal supplements, because they might interact with BACRELBA. In particular, tell your doctor or pharmacist or health care provider if you are using:

- Medicines used to treat bacterial infections such as clarithromycin, telithromycin or troleandomycin.
- Medicines used to treat fungal infections such as itraconazole, ketoconazole or voriconazole.

- Medicines used to treat human immunodeficiency virus (HIV) such as ritonavir, indinavir, nelfinavir or saquinavir.
- Medicines used to treat seizures such as carbamazepine, phenobarbital or phenytoin.
- Medicines used to treat pain or used as sedatives before or during medical or surgical procedures, such as alfentanil or fentanyl.
- Medicines used to treat migraine or dementia, such as dihydroergotamine or ergotamine.
- Medicines that may have an unwanted effect on the electrical activities of the heart (torsades de pointes), such as bepridil, chloroquine, clarithromycin, halofantrine, haloperidol, methadone, moxifloxacin or pimozide.
- Medicines used to reduce the blood's ability to clot, such as warfarin or dabigatran.
- Medicines used to treat severe inflammation of the bowel or severe rheumatic or painful joint inflammation, such as sulfasalazine or colchicine.
- Medicines used to treat cancer, severe rheumatic joint inflammation, or psoriasis, such as methotrexate.
- Rosuvastatin, a medicine used to reduce blood cholesterol levels.
- Medicines used to treat high blood pressure and other heart conditions, such as digoxin.
- St. John's wort (also known as Hypericum perforatum), a herbal medicine used to treat depression and other conditions.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

You should tell your doctor if you are already taking BACRELBA and you are prescribed any new medicine during treatment with BACRELBA.

BACRELBA with food

Do not take BACRELBA with food. Take BACRELBA at least 2 hours after and 1 hour before any food. For more information, see section 3 under “When to take BACRELBA”.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or health care provider for advice before taking this medicine.

Your doctor will discuss with you the potential risks of taking BACRELBA during pregnancy or breastfeeding.

It is not known if BACRELBA passes into your breast milk. Breastfeeding is not recommended during treatment with BACRELBA and for at least 3 days after the last dose.

Females of child-bearing potential and male patients

BACRELBA can harm your unborn baby. If you are a woman of child-bearing age, your doctor, pharmacist or health care provider will check if you are pregnant and perform a pregnancy test if necessary, before starting treatment with BACRELBA.

If you may become pregnant, you should use an effective birth control during treatment with BACRELBA and for at least 3 days after the last dose. Ask your doctor about effective birth control options.

If you become pregnant or think you are pregnant after starting treatment with BACRELBA, tell your health care provider right away.

Driving and using machines

If you experience dizziness or blurred vision after treatment with BACRELBA, do not drive or use machines until you have confirmed that BACRELBA does not affect your performance.

Important information about some ingredients of BACRELBA:

BACRELBA contains lactose (milk sugar). Patients with the rare hereditary condition of lactose or galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take BACRELBA.

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

BACRELBA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take BACRELBA

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

Do not exceed the recommended dose prescribed by your doctor.

How much BACRELBA to take

Your doctor will tell you exactly how many BACRELBA tablets to take and how to take them.

Depending on how you respond to treatment with BACRELBA, your doctor may ask you to change to a lower dose or to temporarily or permanently stop the treatment.

Ph+ CML-CP

The usual total daily dose of BACRELBA is 80 mg (2 tablets of BACRELBA 40 mg per day). You may take your daily dose:

- Once daily: Take 2 tablets at approximately the same time each day or;
- Twice daily: Take 1 tablet, then take another one approximately 12 hours later.

Ph+ CML-CP with the T315I mutation

The usual daily dose of BACRELBA is 200 mg (5 tablets of BACRELBA 40 mg) taken twice daily at approximately 12-hour intervals (10 tablets per day).

You should not change the BACRELBA dose or schedule without first talking to your doctor.

When to take BACRELBA

Taking BACRELBA at the same time each day will help you to remember when to take your medicine.

Take BACRELBA:

- At least 2 hours after any food.
- Then wait at least 1 hour before eating again.

How to take BACRELBA

Swallow BACRELBA tablets whole. Do not break, crush or chew BACRELBA tablets.

How long to take BACRELBA

Continue taking BACRELBA for as long as your doctor tells you.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to take BACRELBA, talk to your doctor, pharmacist or health care provider.

If you take more BACRELBA than you should

If you have taken more BACRELBA than you should have, or if someone else accidentally takes your medicine, contact a doctor or the hospital for advice straight away. Show them the pack of BACRELBA. Medical treatment may be necessary.

If you forget to take BACRELBA

If you take BACRELBA once daily

If you forget to take BACRELBA by more than 12 hours, skip the missed dose and take the next one as usual.

If you take BACRELBA twice daily

If you forget to take BACRELBA by more than 6 hours, skip the missed dose and take the next one as usual.

If you stop taking BACRELBA

Do not stop taking BACRELBA unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or health care provider.

4. Possible side effects

BACRELBA can have side effects.

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

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

- Spontaneous bleeding or bruising (signs of low levels of platelets, thrombocytopenia).
- Fever, sore throat, frequent infections (signs of low levels of white blood cells, neutropenia).
- Irregular heartbeat, change in the electrical activity of the heart (prolongation of the QT interval).
- Fever above 38°C associated with a low level of white blood cells (febrile neutropenia).

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

Tell your doctor if you notice any of the following:

Frequent

- Nose and throat infections (upper respiratory tract infection)
- Tiredness, fatigue, pale skin (potential signs of low level of red blood cells, anaemia)
- Headache
- Dizziness
- Headache, dizziness, chest pain or shortness of breath (signs of high blood pressure, hypertension)
- Cough
- Vomiting
- Diarrhoea
- Nausea
- Abdominal pain
- Constipation
- Rash
- Itching (pruritus)
- Pain in muscles, bones or joints (musculoskeletal pain)

- Joint pain (arthralgia)
- Tiredness (fatigue).

Less frequent

- Fever, coughing, difficulty breathing, wheezing (signs of lower respiratory tract infections)
- Influenza
- Tiredness, weight gain, skin and hair changes (signs of an underactive thyroid gland, hypothyroidism)
- Loss of appetite
- Blurred vision
- Dry eyes
- Palpitations
- Chest pain, cough, hiccups, rapid breathing, fluid collection between the lungs and chest cavity which, if severe, could make you breathless (pleural effusion)
- Shortness of breath, laboured breathing (signs of dyspnoea)
- Chest pain (non-cardiac chest pain)
- Severe upper stomach pain (sign of inflamed pancreas, pancreatitis)
- Itchy rash (urticaria)
- Fever (pyrexia)
- Generalised swelling (oedema).

Uncommon

- Allergic reaction which may include rash, hives, difficulty breathing or low blood pressure (hypersensitivity).

Abnormal blood test results

During BACRELBA treatment, the results of blood tests may be abnormal, which can give your doctor information on the function of your organs. For example:

Frequent

- High level of the enzymes lipase and amylase (pancreas function).
- High level of the enzymes transaminases, which include alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT) (liver function).
- High level of fats/lipids (dyslipidaemia).

Less frequent

- High level of bilirubin (liver function).
- High level of creatine phosphokinase (muscle function).

If you notice any side effects not listed in this leaflet, please inform your doctor, pharmacist or health care provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store BACRELBA

- Store at or below 25 °C.
- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the package.

- Store in the original package in order to protect from moisture.
- Keep this medicine in the carton until required for use.

Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What BACRELBA contains

The active substance of BACRELBA is asciminib.

The excipients of BACRELBA are lactose monohydrate, microcrystalline cellulose (E460i), hydroxypropylcellulose (E463), croscarmellose sodium (E468), polyvinyl alcohol (E1203), titanium dioxide (E171), magnesium stearate, talc (E553b), colloidal silicon dioxide, iron oxide (E172, yellow and red for 20 mg film-coated tablets; black and red for 40 mg film-coated tablets), lecithin (E322), xanthan gum (E415).

What BACRELBA looks like and contents of the pack

BACRELBA is supplied as film-coated tablets in packs containing 20 or 60 film-coated tablets.

Each 20 mg film-coated tablet contains 20 mg asciminib.

BACRELBA 20 mg film-coated tablets are pale yellow, round, biconvex tablets with bevelled edges of approximately 6,2 mm diameter, unscored, debossed with “Novartis” logo on one side and “20” on the other side.

Each 40 mg film-coated tablet contains 40 mg asciminib.

BACRELBA 40 mg film-coated tablets are violet white, round, biconvex tablets with bevelled edges of approximately 8,2 mm diameter, unscored, debossed with “Novartis” logo on one side and “40” on the other side.

Holder of Certificate of Registration

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