Patient Information Leaflet

SCHEDULING STATUS: **S4**

BAXIMO 25 mg powder for concentrate for solution for infusion
One vial contains bendamustine hydrochloride monohydrate equivalent to 25 mg bendamustine hydrochloride.
Contains sugar (40 mg mannitol per vial).
BAXIMO 100 mg powder for concentrate for solution for infusion
One vial contains bendamustine hydrochloride monohydrate equivalent to 100 mg bendamustine hydrochloride.
Contains sugar (160 mg mannitol per vial)
1 mL of the concentrate contains 2,5 mg bendamustine hydrochloride when reconstituted.

Read all of this leaflet carefully before you start using **BAXIMO**.

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

What is in this leaflet

1. What BAXIMO is and what it is used for

BAXIMO is used for treatment of certain types of cancer (cytotoxic medicines).

BAXIMO is used alone (monotherapy) or in combination with other medicines.

2. What you need to know before you use BAXIMO

Do not use BAXIMO

- If you are hypersensitive (allergic) to bendamustine hydrochloride or any of the other ingredients of **BAXIMO** (listed in section 6).
- If you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).
- If you have severe liver disease.
- If you have yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice).
- If you have severely disturbed bone marrow function (bone marrow depression) and serious changes in the number of white blood cells and platelets in your blood.
- If you have had major surgical operations less than 30 days before starting treatment.
- If you have an infection, especially one accompanied by a reduction in white blood cells (leukocytopenia).
- In combination with yellow fever vaccines or any other live vaccines.
- If you have a condition called congenital QT prolongation (a disorder of the heart's electrical system that predisposes to irregular heartbeats or fainting).
- If you are taking medicines causing QT prolongation (see Other medicines and **BAXIMO** section below).

Warnings and precautions

Take special care with BAXIMO

- In case of reduced capability of the bone marrow to replace blood cells. You should have the number of white blood cells and platelets in your blood checked before starting treatment with **BAXIMO**, before each subsequent course of treatment and in the intervals between courses of treatment.
- In case of infections. You should contact your healthcare provider if you have signs of infection, including fever or lung symptoms.
- If you had hepatitis B virus infection in the past. Your doctor will monitor you for signs and symptoms of active hepatitis B virus infection throughout therapy and for several months after stopping treatment with **BAXIMO**.
- In case of reactions on your skin during treatment with **BAXIMO**. The skin reactions may increase in severity.

- In case of painful red or purplish rash that spreads and blisters and/or if other lesions begin to appear in the mucous membrane (e.g. mouth and lips), in particular if you had before light sensitivity, infections of the respiratory system and/or fever.
- In cases of existing heart disease (e.g. heart attack, chest pain, severely disturbed heart rhythms).
- If you experience nausea (feeling sick) or are vomiting (being sick), your doctor may give you an antiemetic to relief these symptoms.
- In case you notice 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 **BAXIMO**. Your doctor may ensure you are adequately hydrated and give you other medicines to help prevent it.
- In case of severe allergic or hypersensitivity reactions. You should pay attention to infusion reactions after your first cycle of therapy.
- If you are female, you should not become pregnant as **BAXIMO** causes genetic damage and malformations to unborn babies. Your doctor will advise you to use effective contraception if you are of childbearing potential.
- If you are male, your doctor will advise the use of effective contraception to avoid conception as **BAXIMO** causes genetic damage and malformations to unborn babies.

Other medicines and BAXIMO

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

If **BAXIMO** is used in combination with medicines which inhibit the formation of blood in the bone marrow, the effect on the bone marrow may be intensified.

If **BAXIMO** is used in combination with medicines which alter your immune response, such as ciclosporin and tacrolimus, this effect may be intensified.

Cytostatic medicines may diminish the effectiveness of vaccination using live viruses. Additionally, cytostatic medicines increase the risk of an infection after vaccination with live vaccines (e.g. viral vaccination).

Fluvoxamine (used for the treatment of obsessive compulsive disorder (OCD), major depressive disorder or anxiety disorders), ciprofloxacin (used to treat bacterial infections), acyclovir (used to treat virus infections) and cimetidine (used to treat heartburn) may cause an interaction with **BAXIMO**.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using **BAXIMO**.

Do not use **BAXIMO** if you are pregnant or breastfeeding.

If you are a woman of childbearing potential, you must use an effective method of contraception both before, during and up to 6 months after completion of treatment (i.e.: after the final dose) with **BAXIMO**. If pregnancy occurs during your treatment with **BAXIMO** you must immediately inform your doctor and should use genetic consultation.

Men being treated with **BAXIMO** are advised not to have a child during and for up to 3 months after completion of treatment (i.e: after the final dose). Because of the possibility of irreversible infertility due to therapy with **BAXIMO**, advice on preserving sperm should be sought before starting with treatment.

Driving and using machines

BAXIMO may make you feel sleepy or dizzy. Do not drive a vehicle or use any tools or machines until you know how **BAXIMO** affects you.

3. How to use BAXIMO

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

Always use this **BAXIMO** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with **BAXIMO** should be undertaken only by doctors experienced in cancer therapy. Your doctor will give you the exact dose of **BAXIMO** and use the necessary precautions.

BAXIMO is administered into a vein over 30 – 60 minutes in various dosages, either alone (monotherapy) or in combination with other medicines.

Treatment should not be started if your white blood cells (leukocytes) and/or your blood platelets have fallen to counts below determined levels.

Your doctor will determine these values at regular intervals.

If you have the impression that the effect of **BAXIMO** is too strong or too weak, tell your doctor or pharmacist.

If you use more BAXIMO than you should

Since a healthcare provider will administer **BAXIMO**, he/she will control the dosage. However, in the event of overdosage your doctor will manage any symptoms of overdosage.

If you stop using BAXIMO

The doctor treating you will decide whether to interrupt the treatment or to change over to a different preparation.

4. Possible side effects

BAXIMO can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, 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 allergic reaction to **BAXIMO**. You may need urgent medical attention or hospitalisation.

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

Side effects that may occur frequently:

- Disturbed function (dysfunction) of the heart.
- Chest pain (angina).
- Disturbed heart rhythms (dysrhythmia).
- Disturbed lung function.

Side effects that may occur less frequently:

- Primary atypical inflammation of the lungs (pneumonia).
- Severe allergic hypersensitivity reactions (anaphylactic or anaphylactoid reactions).
- Accumulation of fluid in the heart sac (escape of fluid into the pericardial space).
- Heart attack, chest pain (myocardial infarction).
- Heart failure.
- Fast irregular heartbeat (tachycardia).
- Acute circulatory collapse (failure of blood circulation mainly from the heart with failure to maintain the supply of oxygen and other nutrients to the tissues and removing toxins).

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:

Side effects that occur frequently:

- Infections (including shingles, cytomegalovirus, hepatitis B virus infection).
- Tumour lysis syndrome (disturbed metabolism caused by dying cancer cells releasing their contents into the bloodstream).
- Low counts of white blood cells (disease-fighting cells in your blood).
- Low counts of platelets (blood cells that help blood clot).

- Bleeding (haemorrhage).
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia).
- Low counts of neutrophils (a common type of white blood cell important for fighting off infections).
- Headache, insomnia (sleeping problems), dizziness.
- Low or high blood pressure (hypotension or hypertension).
- Feeling sick (nausea), being sick (vomiting), diarrhoea, constipation.
- Sore mouth (stomatitis).
- Hair loss (temporary), skin changes, urticaria (hives).
- Missed periods (amenorrhoea).
- Mucosal inflammation.
- Fatigue (unusual weakness or tiredness).
- Fever, pain, chills, dehydration.
- Loss of appetite.
- Decreased haemoglobin level (shortness of breath, irregular heartbeats, dizziness, unusual tiredness).
- Increased blood level of creatinine (a chemical waste product that is produced by your muscle).
- Increased blood level of urea (a chemical waste product).
- A rise in liver enzymes AST/ALT (which may indicate inflammation or damage to cells of the liver).
- A rise in the enzyme alkaline phosphatase (an enzyme made mostly in the liver and bones).
- A rise in bile pigment (a substance made during the normal breakdown of red blood cells).
- Low potassium blood levels (a nutrient that is necessary for the function of nerve and muscle cells, including those in your heart).

Side effects that may occur less frequently:

- Infection of the blood (sepsis).
- Tuberculosis (TB) (a persistent cough, constant tiredness, loss of body mass, loss of appetite, fever, coughing up blood, night sweats).
- Insufficient production of all blood cells in the bone marrow (the spongy material inside your bones where blood cells are made).
- Acute myeloid leukaemia (a cancer of the myeloid line of blood cells, characterised by the rapid growth of abnormal cells that build up in the bone marrow and blood and interfere with normal blood cells).
- Low counts of red and white blood cells, as well as platelets (unusual weakness and bruising).

- Reduction in your bone marrow function, which may make you feel unwell or show up in your blood tests.
- Decrease in the red pigment of the blood (haemoglobin: a protein in red blood cells that carries oxygen throughout the body).
- Drowsiness.
- Loss of voice (aphonia).
- Disturbed sense of taste.
- Altered sensations (paraesthesia).
- Malaise and pain in the limbs (peripheral neuropathy).
- Anticholinergic syndrome (leading to dilated pupils, decreased sweating, elevated temperature or rapid heartbeat).
- Disorders of the nervous system.
- Lack of coordination (ataxia).
- Inflammation of the brain (encephalitis).
- Inflammation of the veins (phlebitis).
- Formation of tissue in the lungs (fibrosis of the lungs).
- Bleeding inflammation of the gullet (haemorrhagic oesophagitis).
- Bleeding of the stomach or intestines.
- Reddening of the skin (erythema).
- Inflammation of the skin (dermatitis).
- Itching (pruritus).
- Skin rash (macular exanthema).
- Excessive sweating (hyperhidrosis).
- Infertility.
- Multiple organ failure.

Side effects that occur with an unknown frequency:

- Inflammation of the lung tissue causing cough, chest pain and or shortness of breath (pneumonitis).
- Bleeding into the tiny air sacs in the lungs causing impaired lung function (pulmonary alveolar haemorrhage).
- Sudden onset of widespread skin blistering, peeling, and severe mucosal damage, often leading to painful sores in the mouth, eyes, and genitals (stevens-johnson syndrome).

- Skin and mucosal blistering and peeling (toxic epidermal necrolysis (TEN)).
- Rash, redness and swelling of the skin, fever, fatigue and or increase in eosinophils, which are a type of white blood cell. (Drug reaction with eosinophilia and systemic symptoms (combination therapy with rituximab)).
- Kidney failure

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects 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 **BAXIMO**.

5. How to store BAXIMO

- Store at or below 30 °C.
- Keep the vial in the outer carton in order to protect from light.
- From a microbiological point of view, **BAXIMO** should be used immediately. If not used immediately, in-use storage times and conditions prior to use, are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
- Discard any unused portion.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **BAXIMO** contains
The active substance is bendamustine hydrochloride.
BAXIMO 25 mg: One vial contains bendamustine hydrochloride monohydrate equivalent to 25 mg bendamustine hydrochloride.
BAXIMO 100 mg: One vial contains bendamustine hydrochloride monohydrate equivalent to 100 mg bendamustine hydrochloride.

After reconstitution, 1 ml of the concentrate contains 2,5 mg bendamustine hydrochloride.

The other ingredient is mannitol.

What BAXIMO looks like and contents of the pack

BAXIMO 25 mg: 25 mL amber type I glass vial with a bromobutyl rubber stopper and an aluminum cap with a flip-top.
Pack size: 1 or 5 vials per outer carton.

BAXIMO 100: 50 mL amber type I glass vial with a bromobutyl rubber stopper and an aluminum cap with a flip-top.
Pack size: 1 or 5 vials per outer carton.

The powder appears white to off-white and crystalline.

Not all pack sizes may be marketed

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK / 232625

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