**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
2. What you need to know before you use **BAXIMO**
3. How to use **BAXIMO**
4. Possible side effects
5. How to store **BAXIMO**
6. Contents of the pack and other information


## 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"**).

**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), 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 **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 mg**: 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

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**Patient Information Leaflet**

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**BAXIMO 25 mg**: 53/26/0304

**BAXIMO 100 mg**: 53/26/0305

adcock ingram

**SKEDULERINGSTATUS:**

**S4**

**BAXIMO 25 mg poeier vir konsentraat vir oplossing vir infusie**
**Een flessie bevat bendamustienhidrochloriedmonohidraat gelykstaande aan 25 mg bendamustienhidrochloried.**
**Bevat suiker (40 mg mannitol per flessie).**
**BAXIMO 100 mg poeier vir konsentraat vir oplossing vir infusie**
**Een flessie bevat bendamustienhidrochloriedmonohidraat gelykstaande aan 100 mg bendamustienhidrochloried.**
**Bevat suiker (160 mg mannitol per flessie)**

1 mL van die konsentraat bevat 2,5 mg bendamustienhidrochloried wanneer hersaamgestel is.

Lees hierdie hele biljet noukeurig deur voordat u **BAXIMO** begin gebruik.
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u enige verdere vrae het, raadpleeg u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

**Wat in hierdie biljet is**

1. Wat **BAXIMO** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **BAXIMO** gebruik
3. Hoe om **BAXIMO** te gebruik
4. Moontlike newe-effekte
5. Hoe om **BAXIMO** te bêre
6. Inhoud van die verpakking en ander inligting

## 1. Wat BAXIMO is en waarvoor dit gebruik word

**BAXIMO** word gebruik vir die behandeling van sekere soorte kanker (sitotoksiese medisyne).
**BAXIMO** word alleen (monoterapie) of in kombinasie met ander medisyne gebruik.

## 2. Wat u moet weet voordat u BAXIMO gebruik

**Moenie BAXIMO gebruik nie**
- Indien u hipersensitief (allergies) is vir bendamustienhidrochloried of enige van die ander bestanddele van **BAXIMO** (gelys in afdeling 6).
- Indien u swanger is of u baba borsvoed (sien Swangerskap en borsvoeding).
- Indien u ernstige lewersiekte het.
- Indien u vergeling van die vel of wit van die oë het wat veroorsaak word deur lewer- of bloedprobleme (geelsug).
- Indien u ernstig versteurde beenmurgfunksie (beenmurgdepressie) en ernstige veranderinge in die aantal witbloedselle en bloedplaatjies in u bloed het.
- Indien u groot chirurgiese operasies gehad het binne minder as 30 dae voor die aanvang van die behandeling.

- Indien u 'n infeksie het, veral een wat gepaard gaan met 'n vermindering in witbloedselle (leukositopenie).
- In kombinasie met geelkoors-entstowwe of enige ander lewendige entstowwe.
- Indien u 'n toestand het wat oorerflike QT-verlenging genoem word ('n versteuring van die hart se elektriese stelsel wat u vatbaarheid maak vir onreëlmatige hartklop of floute).
- Indien u medisyne neem wat QT-verlenging veroorsaak (sien "Ander medisyne en **BAXIMO"**).

**Waarskuwings en voorsorgmaatreëls**

***Wees veral versigtig met BAXIMO***

- In die geval van verminderde vermoë van die beenmurg om bloedselle te vervang. U moet die aantal witbloedselle en bloedplaatjies in u bloed laat nagaan voordat behandeling met **BAXIMO** begin word, voor elke daaropvolgende behandelingskursus en in die tussenposes tussen behandelingskursusse.
- In geval van infeksies. U moet u gesondheidsorgverskaffer kontak indien u tekens van infeksie het, insluitend koors of longsimptome.
- Indien u in die verlede hepatitis B-virusinfeksie gehad het. U dokter sal u monitor vir tekens en simptome van aktiewe hepatitis B-virusinfeksie tydens behandeling en vir 'n paar maande nadat u behandeling met **BAXIMO** gestaak is.
- In geval van reaksies op u vel tydens behandeling met **BAXIMO**. Die velreaksies kan in erns toeneem.
- In die geval van pynlike rooi of perserige uitslag wat versprei en blase en/of as ander letsels in die slymvlies (bv. mond en lippe) begin verskyn, infeksies van die asemhalingstelsel en/of koors.
- In gevalle van bestaande hartsiektes (bv. hartaanval, borspyn, ernstig versteurde hartritmes).
- Indien u naarheid ervaar (naar voel) of braak (opgooi), kan u dokter u 'n anti-emetika gee om hierdie simptome te verlig.
- Indien u bloed in u urien of verminderde hoeveelheid urien opmerk. Wanneer u siekte baie ernstig is, kan u liggaam dalk nie al die afvalprodukte van die sterwende kankerselle opklaar nie. Dit word tumorlise-sindroom genoem en kan nierversaking en hartprobleme veroorsaak binne 48 uur na die eerste dosis **BAXIMO**. U dokter kan verseker dat u voldoende gehidreer is en u ander medisyne gee om dit te help voorkom.
- In geval van ernstige allergiese of hipersensitiwiteitsreaksies. U moet aandag gee aan infusiereaksies na u eerste siklus van terapie.
- Indien u vroulik is, moet u nie swanger raak nie, aangesien **BAXIMO** genetiese skade en misvorming by ongebore babas veroorsaak. U dokter sal u aanraai om effektiewe voorbehoeding te gebruik as u potensieel vrugbaar is.
- Indien u manlik is, sal u dokter die gebruik van effektiewe voorbehoeding aanbeveel om bevrugting te voorkom, aangesien **BAXIMO** genetiese skade en misvorming by ongebore babas veroorsaak.

***Ander medisyne en BAXIMO***

Lig altyd u gesondheidsorgverskaffer in indien u of u kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Indien **BAXIMO** in kombinasie met medisyne gebruik word wat die vorming van bloed in die beenmurg verhinder, kan die effek op die beenmurg versterk word.

Indien **BAXIMO** in kombinasie gebruik word met medisyne wat u immuniteitsreaksie aantas, soos siklosporien en takrolimus, kan hierdie effek versterk word.

Sitostatiese medisyne kan die doeltreffendheid van inenting met behulp van lewende virusse verminder. Daarbenewens verhoog sitostatiese medisyne die risiko van 'n infeksie na inenting met lewende entstowwe (bv. virale inenting).

Fluvoksamien (gebruik vir die behandeling van obsessiewe kompulsiewe versteuring (OCD), ernstige depressiewe versteuring of angsversteurings), siprofloksasien (gebruik om bakteriële infeksies te behandel), asiklovir (gebruik om virusinfeksies te behandel) en simetidien (gebruik om sooibrand te behandel) kan 'n interaksie met **BAXIMO** veroorsaak.

**Swangerskap, borsvoeding en vrugbaarheid**
Indien u swanger is of borsvoed, dink u kan swanger wees of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **BAXIMO** gebruik.

Moenie **BAXIMO** gebruik indien u swanger is of borsvoed nie.

Indien u 'n vrou is wat potensieel vrugbaar is, moet u 'n effektiewe metode van voorbehoeding gebruik, beide voor, tydens en vir tot 6 maande na voltooiing van die behandeling (d.w.s.: na die finale dosis) met **BAXIMO**. Indien swangerskap tydens u behandeling met **BAXIMO** voorkom, moet u dadelik u dokter in kennis stel en genetiese konsultasie gebruik.

Mans wat met **BAXIMO** behandel word, word aangeraai om nie 'n kind te verwek tydens en vir tot 3 maande na voltooiing van die behandeling nie (d.w.s. na die finale dosis). As gevolg van die moontlikheid van onomkeerbare onvrugbaarheid as gevolg van terapie met **BAXIMO**, moet advies oor die bewaring van sperms ingewin word voordat met behandeling begin word.

**Bestuur en gebruik van masjinerie**
**BAXIMO** kan u slaperig of duiselig laat voel. Moenie 'n voertuig bestuur of enige gereedskap of masjinerie hanteer voordat u weet hoe **BAXIMO** u beïnvloed nie.

**3. Hoe om BAXIMO te gebruik**
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie. Gebruik altyd **BAXIMO** presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Behandeling met **BAXIMO** moet slegs onderneem word deur dokters wat ervare is in kankerterapie. U dokter sal die presiese dosis **BAXIMO** aan u toedien en die nodige voorsorgmaatreëls tref.

**BAXIMO** word oor 30 – 60 minute in verskillende dosisse binne-in 'n aar toegedien, hetsy alleen (monoterapie) of in kombinasie met ander medisyne.

Behandeling moet nie begin word indien u witbloedselle (leukosiete) en/of u bloedplaatjies tot tellings onder bepaalde vlakke gedaal het nie.
U dokter sal hierdie waardes met gereelde tussenposes bepaal.
Indien u die indruk het dat die effek van **BAXIMO** te sterk of te swak is, lig u dokter of apteker in.

**Indien u meer BAXIMO gebruik indien wat u moes**
Aangesien 'n gesondheidsorgverskaffer **BAXIMO** sal toedien, sal hy/sy die dosis beheer. In die geval van oordosering sal u dokter egter enige simptome van oordosering hanteer.

**Indien u ophou om BAXIMO te gebruik**
Die dokter wat u behandel sal besluit of u die behandeling moet onderbreek of na 'n ander geneesmiddel moet oorskakel.

**4. Moontlike newe-effekte**
**BAXIMO** kan newe-effekte hê.
Nie alle newe-effekte wat vir **BAXIMO** aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u **BAXIMO** neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

**Indien enige van die volgende gebeur, hou op om BAXIMO te neem en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:**
- Swelling van u hande, voete, enkels, gesig, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Veluitslag of jeukerigheid.
- Floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op **BAXIMO** gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

**Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:**
***Newe-effekte wat gereeld kan voorkom:***
- Versteurde funksie (disfunksie) van die hart.
- Borspyn (angina).
- Versteurde hartritmes (disritmie).
- Versteurde longfunksie.

***Newe-effekte wat minder gereeld kan voorkom:***
- Primêre atipiese inflammasie van die longe (longontsteking).
- Ernstige allergiese hipersensitiwiteitsreaksies (anafilaktiese of anafilakse-tipe reaksies).
- Opeenhoping van vloeistof in die hartsak (ontsnapping van vloeistof in die perikardiale ruimte).
- Hartaanval, borspyn (miokardiale infarksie).
- Hartversaking.
- Vinnige onreëlmatige hartklop (tagikardie).

- Akute bloedsomloop-ineenstorting (mislukking van bloedsomloop hoofsaaklik vanaf die hart met onvermoë om die toevoer van suurstof en ander voedingstowwe na die weefsels te handhaaf en gifstowwe te verwyder).

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp benodig.

**Lig u dokter so gou as moontlik in indien u enige van die volgende opmerk:**
***Newe-effekte wat gereeld voorkom:***

- Infeksies (insluitend gordelroos, sitomegalovirus, hepatitis B-virusinfeksie).
- Tumorlise-sindroom (versteurde metabolisme wat veroorsaak word deur sterwende kankerselle wat hul inhoud in die bloedstroom vrystel).
- Lae witbloedsel-tellings (siektebestrydende selle in u bloed).
- Lae bloedplaatjie-tellings (bloedselle wat bloed help stol).
- Bloeding (hemoragie).
- Vermindering in rooibloedselle wat die vel bleek kan maak en swakheid of kortasem (bloedarmoede) kan veroorsaak.
- Lae neutrofiel-tellings ('n algemene tipe witbloedsel wat belangrik is vir die bekamping van infeksies).
- Hoofpyn, insomnia (slaapprobleme), duiseligheid.
- Lae of hoë bloeddruk (hipotensie of hipertensie).
- Naargevoel (naarheid), opgooi (braking), diarree, hardlywigheid.
- Seer mond (stomatitis).
- Haarverlies (tydelik), velveranderinge, urtikaria (galbulte).
- Oorgeslaande menstruasies (amenoree).
- Mukosale inflammasie.
- Moegheid (ongewone swakheid of moegheid).
- Koors, pyn, kouekoors, dehidrasie.
- Verlies aan eetlus.
- Verlaagde hemoglobienvlak (kortasem, onreëlmatige hartslag, duiseligheid, ongewone moegheid).
- Verhoogde bloedvlak van kreatinien ('n chemiese afvalproduk wat deur u spiere geproduseer word).
- Verhoogde bloedvlak van ureum ('n chemiese afvalproduk).
- 'n Toename in lewerensieme AST/ALT (wat inflammasie of skade aan selle van die lewer kan aandui).
- 'n Styging in die ensiem alkaliese fosfatase ('n ensiem wat meestal in die lewer en bene gemaak word).
- 'n Styging in galpigment ('n stof wat tydens die normale afbraak van rooibloedselle gemaak word).
- Lae kaliumbloedvlakke ('n voedingstof wat nodig is vir die funksie van senuwee- en spierselle, insluitend dié in u hart).

***Newe-effekte wat minder gereeld kan voorkom:***

- Infeksie van die bloed (sepsis).

- Tuberkulose (TB) ('n aanhoudende hoes, konstante moegheid, verlies aan liggaamsmassa, verlies aan eetlus, koors, uithoes van bloed, nagsweet).
- Onvoldoende produksie van alle bloedselle in die beenmurg (die sponsagtige materiaal in u bene waar bloedselle gemaak word).
- Akute miëloïed leukemie ('n kanker van die miëloïed-lyn bloedselle, gekenmerk deur die vinnige groei van abnormale selle wat in die beenmurg en bloed opbou en inmeng met normale bloedselle).
- Lae tellings van rooi- en witbloedselle, sowel as bloedplaatjies (ongewone swakheid en kneusplekke).
- Vermindering in u beenmurgfunksie, wat u onwel kan laat voel of in u bloedtoetse kan verskyn.
- Afname in die rooi pigment van die bloed (hemoglobien: 'n proteïen in rooibloedselle wat suurstof dwarsdeur die liggaam dra).
- Lomerigheid.
- Verlies van stem (afonie).
- Versteurde smaaksintuig.
- Veranderde sensasies (parestesie).
- Malaise en pyn in die ledemate (perifere neuropatie).
- Anticholinergiese sindroom (wat lei tot verwyde pupille, verminderde sweet, verhoogde temperatuur of vinnige hartklop).
- Versteurings van die senuweestelsel.
- Gebrek aan koördinasie (ataksie).
- Inflammasie van die brein (enkefalitis).
- Inflammasie van die are (flebitis).
- Vorming van weefsel in die longe (fibrose van die longe).
- Bloeding-inflammasie van die slukderm (hemoragiese esofagitis).
- Bloeding van die maag of ingewande.
- Rooiheid van die vel (eriteem).
- Inflammasie van die vel (dermatitis).
- Jeukerigheid (pruritus).
- Veluitslag (makulêre eksanteem).
- Oormatige sweet (hiperhidrose).
- Onvrugbaarheid.
- Veelvuldige orgaanversaking.

***Newe-effekte wat met 'n onbekende frekwensie voorkom:***

- Inflammasie van die longweefsel wat hoes, borspyn en of kortasem (longontsteking) veroorsaak.
- Bloeding in die klein lugsakkies in die longe wat verswakte longfunksie veroorsaak (pulmonale alveolêre bloeding).
- Skielike aanvang van wydverspreide blase op die vel, afskilfering en ernstige slymvliesskade, wat dikwels lei tot pynlike sere in die mond, oë en geslagsdele (Stevens-Johnson se sindroom).
- Afskilfering van, en blase op die vel en slymvliese (toksiese epidermale nekrolise (TEN)).

- Uitslag, rooiheid en swelling van die vel, koors, moegheid en of toename in eosinofiele, wat 'n tipe witbloedselle is. (Geneesmiddelreaksie met eosinofilie en sistemiese simptome (kombinasieterapie met rituximab)).
- Nierversaking

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

**Aanmelding van newe-effekte:**
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektroniese aanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **BAXIMO** te verskaf.

**5. Hoe om BAXIMO te bêre**
- Bêre teen of benede 30 °C.
- Hou die flessie in die buitenste kartonboksie om teen lig te beskerm.
- Vanuit 'n mikrobiologiese oogpunt moet **BAXIMO** onmiddellik gebruik word. Indien dit nie onmiddellik gebruik word nie, is bergingstye tydens gebruik en bergingstoestande voor gebruik die verantwoordelikheid van die gebruiker en sal normaalweg nie langer as 24 uur by 2 – 8 °C wees nie, tensy hersamestelling/verdunning in beheerde en gevalideerde aseptiese toestande plaasgevind het.
- Gooi enige ongebruikte gedeelte weg.
- BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die etiket of kartonboksie gedruk is nie.
- Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) weggooi nie.

**6. Inhoud van die verpakking en ander inligting**
Wat **BAXIMO** bevat
Die aktiewe bestanddeel is bendamustienhidrochloried.
**BAXIMO** 25 mg: Een flessie bevat bendamustienhidrochloriedmonohidraat gelykstaande aan 25 mg bendamustienhidrochloried.
**BAXIMO** 100 mg: Een flessie bevat bendamustienhidrochloriedmonohidraat gelykstaande aan 100 mg bendamustienhidrochloried.

Na hersamestelling bevat 1 mL van die konsentraat 2,5 mg bendamustienhidrochloried.
Die ander bestanddeel is mannitol.

**Hoe BAXIMO lyk en inhoud van die verpakking**
**BAXIMO 25 mg:** 25 mL amber tipe-I glasflessie met 'n broombutiel-rubberprop en 'n aluminiumdop met 'n afwip-proppie.
Verpakkingsgrootte: 1 of 5 flessies per buitenste kartonboksie.

**BAXIMO 100 mg:** 50 mL amber tipe-I glasflessie met 'n broombutiel-rubberprop en 'n aluminiumdop met 'n afwip-proppie.

Verpakkingsgrootte: 1 of 5 flessies per buitenste kartonboksie.
Die poeier lyk wit tot naaswit en kristallyn.
Nie alle verpakkingsgroottes word dalk bemark nie.

**Houer van Sertifikaat van Registrasie**
Adcock Ingram Limited
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Midrand,
1685
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**Hierdie biljet is mees onlangs hersien op**
05 Junie 2025

**Registrasienommer**
**BAXIMO 25 mg:** 53/26/0304
**BAXIMO 100 mg**: 53/26/0305