Applicant : Eurolab (Pty) Ltd
Proprietary name : Pomaxel 1 mg & 2 mg & 3 mg & 4 mg
Dosage form and strength : Capsules 1 mg & 2 mg & 3 mg & 4 mg
Date of submission : 28 February 2024

SCHEDULING STATUS: S4

POMAXEL 1 mg, 2 mg, 3 mg & 4 mg capsules

Pomalidomide

Contains sugar: Isomalt

POMAXEL is expected to cause severe birth defects and may lead to the death of an unborn baby.

- Do not take this medicine if you are pregnant or could become pregnant.
- You must follow the contraception advice described in this leaflet.

Read all of this leaflet carefully before you start taking POMAXEL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **POMAXEL** 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 **POMAXEL** is and what it is used for
2. What you need to know before you take **POMAXEL**
3. How to take **POMAXEL**
4. Possible side effects
5. How to store **POMAXEL**
6. Contents of the pack and other information

1 What POMAXEL is and what it is used for

POMAXEL contains the active substance 'pomalidomide'. This medicine is related to thalidomide and belongs to a group of medicines which affect how your immune system works (your body's natural defences).

POMAXEL is used to treat adults with a type of cancer called 'multiple myeloma'.

POMAXEL is either taken:

- with two other medicines called 'bortezomib' and 'dexamethasone' to treat adult patients with a type of cancer called 'multiple myeloma'. It is used in people who have received at least one previous treatment including a product called 'lenalidomide'.
- with one other medicine, called 'dexamethasone' (a type of medicine to treat inflammatory and autoimmune disorders), in people whose myeloma has become worse, despite having at least two other treatments, including both lenalidomide and a proteasome inhibitor, e.g. bortezomib.

What is multiple myeloma

Multiple myeloma is a type of cancer, which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

POMAXEL can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

2 What you need to know before you take POMAXEL

Do not take POMAXEL

- if you are allergic to pomalidomide or any of the other ingredients of **POMAXEL** (listed in section 6).

- if you are pregnant, think you may be pregnant or are planning to become pregnant, as **POMAXEL** is expected to be harmful to an unborn child (men and women to read section 2, '**Pregnancy, breastfeeding and fertility**', below).
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see section 2, '**Pregnancy, breastfeeding and fertility**'). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation.

Warnings and Precautions

Special care should be taken with **POMAXEL**:

- if you are pregnant, think you may be pregnant or are planning to become pregnant, as **POMAXEL** is expected to be harmful to an unborn child (see section 2, '**Pregnancy, breastfeeding and fertility**').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see section 2, 'Pregnancy, breastfeeding and fertility'). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation.
- even if you suffer from amenorrhoea (absence of menstruation), resulting from cancer therapy or during breast-feeding, as it doesn't rule out becoming pregnant.
- if you are a male patient, you should be aware of the risk engaging in sexual activity with a woman of childbearing potential.
- if a woman becomes pregnant while the male patient is taking or 4 weeks after he has stopped taking **POMAXEL**, he must inform his treating doctor immediately.

- if the woman is not using effective contraception, use of condoms is necessary (even if you had a vasectomy) with a pregnant woman or woman of childbearing potential, during the course of the treatment, during dose interruption and for 4 weeks after treatment.
- if you are able to become pregnant, at least two reliable contraception methods should be used for at least 4 weeks before starting therapy, during and until at least 4 weeks after therapy.
- if you have had blood clots in the past or using oral contraceptives - you have an increased risk of developing blood clots in the veins and arteries during treatment.
- if you obtained additional contraceptive therapy (implants or devices), you have an increased risk of infection and irregular bleeding. Antibiotics should be considered, especially if you suffer from neutropenia (abnormally low count of white blood cells).
- Inserting of a copper-releasing intrauterine device is not recommended, as you have an increased risk of infection, at the time of insertion and menstrual blood loss, especially if you suffer from severe neutropenia (abnormally low count of white blood cells) or thrombocytopenia (low blood platelet count).
- you should not donate blood, semen or sperm during therapy or for at least 4 weeks after stopping the treatment.
- if you suffer from abnormally low count of a type of white blood cells (neutropenia). Common symptoms include fever, mouth ulcers and sore throat.
- if you experience bleeding, including a nosebleed or are taking other medicine that increases the risk of bleeding.
- if you have ever had blood clots in the past. Treatment with **POMAXEL** may increase the risk of getting blood clots in your veins and arteries. Your doctor may recommend you take additional treatments (e.g. warfarin) or lower the dose of **POMAXEL** to reduce the chances of getting blood clots.
- if you experience tiredness, cold sensitivity, constipation, dry skin and unexplained weight gain, it can be symptoms of hypothyroidism.

- if you experience pain, pins-and-needles sensation, numbness and weakness, it can be signs of peripheral neuropathy.
- if you have had a heart attack, have heart failure, have difficulty breathing or if you smoke, have high blood pressure or high cholesterol levels.
- if you experience nausea, vomiting, diarrhoea, muscle cramps, weakness, numbness or tingling, tiredness, irritability, decreased urination, irregular heart rate, confusion, restlessness, delirium, hallucinations or seizures, it can be signs of Tumour Lysis Syndrome (TLS).
- it is important to note that patients may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed this medicine.
- if you experience a combination of any of the following symptoms: widespread rash, blisters, peeling, red skin, high body temperature, tiredness, flu-like symptoms, sore throat, coughing, itching, mouth-ulcers, it may be signs of Steven Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (see also section 4 '**Possible side effects**').
- if you ever had an allergic reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'.
- if you experience dizziness and confusion.
- if you experience a persistent dry cough, shortness of breath either at rest or after exertion. These symptoms can be due to inflammation of the lungs (pneumonitis) or Interstitial lung disease (ILD), that leads to irreversible damage to your lungs.
- if you suffer from liver failure or any other liver function abnormalities.
- if you have or have ever had previous viral infection, particularly hepatitis B infection. Treatment with **POMAXEL** may cause the hepatitis B virus to become active again in patients who carry the virus, resulting in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.

- at any time during or after treatment, tell your doctor or nurse immediately if you experience general weakness, clumsiness and balance issues, sensory loss, difficulty using arms and legs, changes in vision, loss of language skills, facial drooping, personality changes or memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with pomalidomide, tell your doctor immediately about any change in these symptoms.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Tests, checks and donations

You should not donate blood during treatment and for 4 weeks after the end of treatment.

Before and during the treatment with **POMAXEL** you will have regular blood tests. This is because **POMAXEL** may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).

Your doctor will ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that

As a result of these tests, your doctor may change your dose of **POMAXEL** or stop your treatment. The doctor may also change the dose or stop **POMAXEL** because of your general health concerns.

Due to **POMAXEL** that can harm an unborn child, a medically supervised pregnancy test will need to be performed during your consultation, when **POMAXEL** is prescribed, or at least 7

days prior to your visit to your prescribing doctor once you have been using effective contraception for at least 4 weeks.

Follow-up pregnancy tests should be repeated at least every 4 weeks, including at least 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation.

Children and adolescents

POMAXEL is not recommended for use in children and adolescents under 18 years.

Other medicines and POMAXEL

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

In particular, tell your doctor or nurse if you are taking any of the following medicines:

- some antifungal medicines, such as ketoconazole,
- certain antibiotics (for example ciprofloxacin, enoxacin),
- certain anti-depressants, such as fluvoxamine,
- medicine used as a blood-thinner, such as warfarin.

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 taking this medicine.

Pregnancy

As per the Eurolab Pregnancy Protection Programme, the below must be followed:

Women and men taking **POMAXEL**, must not become pregnant or father a child. This is due to **POMAXEL** expected to be harmful to the unborn baby. While taking **POMAXEL**, you and your partner should use effective methods of contraception.

Women

Do not take **POMAXEL** if you are pregnant, think you may be pregnant or are planning to become pregnant.

The reason is that this medicine is expected to cause harm to the unborn baby. Before starting the treatment, you should tell your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant:

- you must use effective methods of contraception for at least 4 weeks before starting treatment, for the entire time that you are taking **POMAXEL**, and until at least 4 weeks after stopping **POMAXEL**. Talk to your doctor about the best method of contraception for you.
- your doctor will arrange pregnancy tests before treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished.

If you become pregnant despite the prevention measures taken:

- you must stop the treatment immediately and talk to your doctor right away.

Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Men

POMAXEL is present in human semen.

- If your partner is pregnant or able to become pregnant, you must use condoms for the entire time you are taking **POMAXEL** and for 7 days after the end of treatment.
- If your partner becomes pregnant while you are taking **POMAXEL**, tell your doctor immediately.

Your partner should also tell her doctor right away.

You should not donate semen or sperm during treatment and for 7 days after the end of treatment.

Breast-feeding

You should not breast-feed when using **POMAXEL**. It is not known if this medicine passes into human milk.

Fertility

POMAXEL has a negative effect on fertility.

Driving and using machines

Do not drive or operate machines if you feel dizzy, tired, sleepy, feel like fainting or confused after taking **POMAXEL**.

It is not always possible to predict to what extent **POMAXEL** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **POMAXEL** affects them.

POMAXEL contains sodium

POMAXEL contains less than 1 mmol sodium (23 mg) per capsule, therefore it is considered essentially ‘sodium-free’.

POMAXEL contains sugar

POMAXEL contains sugar (isomalt), that may have a mild laxative effect.

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

3 How to take POMAXEL

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

POMAXEL must be given to you by a doctor with experience in treating multiple myeloma.

POMAXEL is taken in combination with another medicine called dexamethasone or bortezomib. See the leaflet that comes with the other medicines for further information on its use and effects.

Always take **POMAXEL** exactly as your doctor has told you. Check with your doctor if you are unsure.

When to take POMAXEL with other medicines

POMAXEL with bortezomib and dexamethasone

- **POMAXEL**, bortezomib and dexamethasone are taken in ‘treatment cycles’. Each cycle lasts 21 days (3 weeks).
- After completing each 3-week cycle, start a new one.

POMAXEL with dexamethasone only

- **POMAXEL** and dexamethasone are taken in ‘treatment cycles’. Each cycle lasts 28 days (4 weeks).
- After completing each 4-week cycle, start a new one.

How much POMAXEL to take with other medicines:

POMAXEL with bortezomib and dexamethasone

- The recommended starting dose of **POMAXEL** is 4 mg per day.
- The recommended starting dose of bortezomib will be worked out by your doctor and based on your height and weight (1,3 mg/m^2 body surface area).
- The recommended starting dose of dexamethasone is 20 mg per day. However, if you are over 75, the recommended starting dose is 10 mg per day.

POMAXEL with dexamethasone only

- The recommended dose of **POMAXEL** is 4 mg per day.
- The recommended starting dose of dexamethasone is 40 mg per day. However, if you are over 75, the recommended starting dose is 20 mg per day.

Your doctor may need to reduce the dose of **POMAXEL**, bortezomib or dexamethasone or stop one or more of these medicines based on the results of your blood tests, your general condition, other medicines you may be taking (e.g. ciprofloxacin, enoxacin and fluvoxamine) and if you experience side effects (especially rash or swelling) from treatment.
If you suffer from liver or kidney problems your doctor will check your condition very carefully whilst you are receiving this medicine.

How to take POMAXEL

POMAXEL should be taken by mouth at about the same time each day. The capsules should not be opened, broken, or chewed. If powder from a broken capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance

with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

POMAXEL capsules should be swallowed whole, preferably with water, either with or without food.

Duration of the treatment with POMAXEL

Your doctor will tell you how long your treatment with **POMAXEL** will last. Do not stop treatment early. If you have the impression that the effect of **POMAXEL** is too strong or too weak, tell your doctor or pharmacist.

If you take more POMAXEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take POMAXEL

If you forget to take **POMAXEL** on a day when you should, take your next capsule as normal the next day. Do not take / receive a double dose to make up for forgotten individual doses.

4 Possible side effects

POMAXEL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects listed above. If you have them, you may have had a serious reaction to **POMAXEL**. 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:

- Flu-like symptoms, fever, shivering, change in behaviour or skin rash, that can be all signs of life-threatening Neutropenic sepsis (low white blood cells in the blood).
- Abnormal bleeding due to low blood platelet count (thrombocytopenia or pancytopenia).
- Low blood levels of sodium, which may cause tiredness and confusion, muscle twitching, fits (epileptic seizures) or coma.
- Brain bleed – symptoms include headache, nausea and vomiting, sudden tingling, weakness, numbness or paralysis of face, arm or leg.
- Heart failure – symptoms include shortness of breath, tiredness, swollen legs and rapid heartbeat.
- Heart attack – symptoms include tightness or pain in the chest, neck, back or arms as well as tiredness, light-headedness, abnormal heartbeat and anxiety.
- Shortness of breath, chest pain and cough, that can be signs of a blood clot in the lung.
- Gastrointestinal bleeding (severe, persistent or bloody diarrhoea (possibly with stomach pain or fever) caused by bacteria called *Clostridium difficile*).

- Decreased urination, swelling, nausea, tiredness and shortness of breath (due to infection of blood called sepsis or septic shock).
- Tumour Lysis Syndrome (TLS) – symptoms include nausea, vomiting, diarrhoea, muscle cramps, weakness, numbness or tingling, tiredness, irritability, decreased urination, irregular heart rate, confusion, restlessness, delirium, hallucinations or seizures.
- Trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg (stroke).
- Widespread rash, blisters, peeling, red skin, high body temperature, tiredness, flu-like symptoms, sore throat, coughing, itching, mouth-ulcers, it may be signs of Steven Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- Neutropenia, febrile neutropenia, pancytopenia or leukopenia (fever, mouth ulcer, sore throat, or susceptibility to infection due to low white blood cell count).
- Depressed level of consciousness.
- Yellowing of the skin and whites of the eyes, darkening of urine, sometimes to a brownish tone or/and abdominal pain, nausea, tiredness.
- Hepatitis B reactivation (yellowing of the eyes or skin (jaundice), loss of appetite, nausea or vomiting, lighter coloured stools, pain in the liver).

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Pneumonia, Bronchopneumonia, Bronchitis, Respiratory tract infection or Upper respiratory tract infection (infection that inflames the air sacs in one or both lungs, that can be due to bacterial, viral or fungal infections, including opportunistic infections).
- Cold symptoms due to Nasopharyngitis (common viral infection of the nose and throat).

- Herpes zoster (painful rash that may appear as a stripe of blisters on the torso).
- Tiredness, skin paleness, shortness of breath, light-headedness, dizziness or a fast heartbeat, due to low red blood cell count (anaemia pr pancytopenia).
- Angioedema (swelling of the deeper layers of the skin, caused by a build-up of fluid).
- Hives (itchy, raised, red or skin-coloured welts on the skin's surface).
- Decreased appetite.
- High blood levels of potassium, which may cause abnormal heart rhythm.
- High blood levels of uric acid, which may cause severe pain in joints, joint stiffness, redness and swelling.
- Confusional state.
- Weakness, numbness and pain from nerve damage, usually in the hands and feet (peripheral sensory neuropathy).
- Dizziness.
- Involuntary shaking or movement.
- Dizziness/ vertigo.
- Irregular, rapid heart rate.
- Leg pain or swelling, that can be signs of a blood clot.
- Shortness of breath.
- Cough.
- Nosebleed.
- Diarrhoea, nausea, constipation or vomiting.
- Rash.
- Itchy skin.
- Bone pain.
- Muscle spasms.
- Difficulty urinating.

- Pain or discomfort, ranging from a sharp jab to a dull ache, in the lowest part of the abdomen and pelvis.
- Tiredness.
- Fever.
- Swelling of the lower legs or hands.
- Increased Alanine aminotransferase (ALT). An ALT test measures the amount of this enzyme in the blood. Higher-than-normal levels of ALT can indicate liver damage.

Less frequent side effects:

- Interstitial lung disease (scarring of the lungs). Symptoms include a dry cough and shortness of breath.
- Basal cell carcinoma or squamous cell carcinoma (types of skin cancer).
- Underactive thyroid, that include symptoms such as fatigue, cold sensitivity, constipation, dry skin and unexplained weight gain.

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. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **POMAXEL**.

5 How to store POMAXEL

- Store all medicines out of reach of children.
- Store at or below 30 °C. Keep in the original packaging until required for use.

- Do not use after the expiry date stated on the label / carton.
- Do not use **POMAXEL** if you notice any visible signs of deterioration.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What POMAXEL contains

The active substance is pomalidomide.

The other ingredients are: Isomalt, pregelatinized starch, sodium stearyl fumarate.

The 1 mg capsule shells contain Gelatin, yellow iron oxide, titanium dioxide.

The 2 mg capsule shells contain Gelatin, titanium dioxide, red iron oxide, yellow iron oxide.

The 3 mg capsule shells contain Gelatin, titanium dioxide, Brilliant blue FCF-FD&C Blue 1(1).

The 4 mg capsule shells contain Gelatin, titanium dioxide, FD&C Red #3, Brilliant blue FCF-FD&C Blue 1.

The printing ink on all capsule shells contain Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide, black iron oxide.

What POMAXEL looks like and contents of the pack

POMAXEL 1 MG capsules

Yellow opaque cap and yellow opaque body, capsule shell size No. 4 imprinted in black ink with “LP” on the cap and “664” on the body.

POMAXEL 2 MG capsules

Orange opaque cap and orange opaque body, capsule shell size No. 3 imprinted in black ink with “LP” on the cap and “665” on the body.

POMAXEL 3 MG capsules

Powder blue opaque cap and powder blue opaque body, capsule shell size No. 2 imprinted in black ink with “LP” on the cap and “690” on the body.

POMAXEL 4 MG capsules

Blue opaque cap and blue opaque body, capsule shell size No. 2 imprinted in black ink with “LP” on the cap and “667” on the body.

POMAXEL is packed in PVC/Aclar-Aluminum blisters and Aluminum-Aluminum blisters.

Pack size: 21 capsules (7 capsules x 3 blisters) per box and 40 capsules (8 capsules x 5 blisters) per box.

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

Woodmead Office Park,

3 Stirrup Lane, Van Reenens Avenue,

Woodmead, 2144

This leaflet was last revised in

24 April 2024

Registration number

POMAXEL 1 mg: 56/32/0721

POMAXEL 2 mg: 56/32/0722

Applicant : Eurolab (Pty) Ltd
Proprietary name : Pomaxel 1 mg & 2 mg & 3 mg & 4 mg
Dosage form and strength : Capsules 1 mg & 2 mg & 3 mg & 4 mg
Date of submission : 28 February 2024

POMAXEL 3 mg: 56/32/0723

POMAXEL 4 mg: 56/32/0724