Applicant : Eurolab (Pty) Ltd
Proprietary name : Eurolen 5 mg & 10 mg & 15 mg & 25 mg
Dosage form and strength : Hard capsules 5 mg & 10 mg & 15 mg & 25 mg
Date of submission : 13 September 2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EUROLEN 5 mg, 10 mg, 15 mg & 25 mg Hard capsules

Lenalidomide

(Contains Lactose)

Read all of this leaflet carefully before you start taking EUROLEN

- 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.
- **EUROLEN** 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 **EUROLEN** is and what it is used for
2. What you need to know before you take **EUROLEN**
3. How to take **EUROLEN**
4. Possible side effects
5. How to store **EUROLEN**
6. Contents of the pack and other information

1 What EUROLEN is and what it is used for

What EUROLEN is

EUROLEN contains the active substance ‘lenalidomide’. This medicine belongs to a group of medicines which affect how your immune system works.

What EUROLEN is used for

EUROLEN is used in adults for:

1. Myelodysplastic syndromes (MDS)

2. Multiple myeloma

Myelodysplastic syndromes (MDS)

MDS are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.

EUROLEN is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:

- you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anaemia')
- you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
- other treatments have been used before, are not suitable or do not work well enough.

EUROLEN can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:

- this can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

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.

EUROLEN is taken together with an anti-inflammatory medicine called 'dexamethasone'.

EUROLEN 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 EUROLEN

Do not take EUROLEN

- if you are allergic to lenalidomide or any of the other ingredients of **EUROLEN** (listed in section 6).
- if you are pregnant, think you may be pregnant or are planning to become pregnant, as EUROLEN 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.
- if you are breastfeeding.

Warnings and Precautions

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

- if you are pregnant, think you may be pregnant or are planning to become pregnant, as **EUROLEN** 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.
- if you are a male patient, you should be aware of the risk engaging in sexual activity with a woman of childbearing potential.
- if the women 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.
- if you are a male patient, you should not donate sperm or semen during treatment, including dose interruptions and for 3 months following the end of treatment.
- 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).
- you should not donate blood during therapy or for at least 4 weeks following suspension of lenalidomide.
- if you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels.
- 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) or toxic epidermal necrolysis (TEN) (see also section 4 "Possible side effects").
- if you experience nausea, vomiting, diarrhoea, muscle cramps, weakness, numbness or tingling, tiredness, irritability, decreased urination, it can be signs of Tumour Lysis Syndrome (TLS) and tumour flare reaction (TFR).

- if you suffer from abnormally low count of a type of white blood cells (neutropenia). Common symptoms include fever, mouth ulcers and sore throat.
- a low number of platelets in your blood (thrombocytopenia). Symptoms include easy bruising, superficial bleeding, prolonged bleeding, bleeding from gums or nose and blood in urine.
- if you experience tiredness, cold sensitivity, constipation, dry skin and unexplained weight gain, it can be symptoms of hypothyroidism.
- If you experience unexpected weight loss, rapid or irregular heartbeat, sweating and irritability, it can be signs of hyperthyroidism.
- if you experience pain, pins-and-needles sensation, numbness and weakness, it can be signs of peripheral neuropathy.
- if you experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat or swelling in the legs or ankles. These may be symptoms of a serious condition known as pulmonary hypertension.
- if you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness or trouble breathing.
- if you suffer from liver failure or any other liver function abnormalities.
- if you have kidney problems - your doctor may adjust your dose of **EUROLEN**.
- if you are prone to develop infections, including pneumonia symptoms, e.g. coughing, fever, etc.
- if you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HIV. If you are in doubt, talk to your doctor. Treatment with **EUROLEN** may cause the virus to become active again, in patients who carry the virus. This results in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- 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

or personality changes. 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 lenalidomide, tell your doctor immediately about any change in these symptoms.

- if you suffer from cataracts – main symptom is blurry vision.
- if you suffer from lactose intolerance, as **EUROLEN** contains lactose.

Tests and checks

Before and during the treatment with **EUROLEN** you will have regular blood tests. This is because **EUROLEN** 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

Children and adolescents

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

Other medicines and EUROLEN

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:

- medicine which stimulate the bone marrow to make red blood cells (erythropoietic agents). These medicines are used to treat anaemia due to end stage kidney disease, chemotherapy, major surgery or certain treatments in HIV/AIDS.

- some medicines used to prevent pregnancy such as oral contraceptives that can stop the effectiveness, or hormone replacement therapy.
- some medicines used to thin the blood – such as warfarin.
- some medicines used for heart problems – such as digoxin.
- statins, a cholesterol-lowering medicine.

Pregnancy, breastfeeding and fertility

Pregnancy

For women taking **EUROLEN**

- You must not take **EUROLEN** if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking **EUROLEN**. Therefore, you must use effective methods of contraception if you are a woman of childbearing potential (see 'Contraception').
- If you do become pregnant during your treatment with **EUROLEN**, you must stop the treatment and inform your doctor immediately.

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 **EUROLEN**.

For men taking **EUROLEN**

- If your partner becomes pregnant whilst you are taking **EUROLEN**, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.
- You must also use effective methods of contraception (see 'Contraception').

Breast-feeding

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

Contraception

For women taking **EUROLEN**

Before starting the treatment, ask your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant

- you will have pregnancy tests under the supervision of your doctor (before every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilisation)

AND

- you must use effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and until at least 6 months after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking **EUROLEN**

EUROLEN passes into human semen. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and for at least 3 months after the end of treatment, even if you have had a vasectomy.

Fertility

EUROLEN has no effect on fertility.

Driving and using machines

Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking **EUROLEN**.

It is not always possible to predict to what extent **EUROLEN** 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 **EUROLEN** affects them.

EUROLEN contains lactose

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

3 How to take EUROLEN

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

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

EUROLEN should be taken by mouth at about the same time each day. The capsules should not be opened, broken, or chewed. **EUROLEN** capsules should be swallowed whole, preferably with water, either with or without food.

Myelodysplastic syndromes (MDS):

Recommended dose:

The recommended starting dose of **EUROLEN** is 10 mg once daily, on days 1-21 of a 28-day repeatable treatment cycle.

Multiple Myeloma

Recommended dose:

The recommended starting dose of **EUROLEN** is 25 mg per day on days 1-21 of a 28-day repeatable cycle.

The recommended dose for dexamethasone is 40 mg per day on Days 1-4, 9-12, and 17-20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg per day on days 1-4 every 28 days.

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

If you take more EUROLEN 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 EUROLEN

If less than 12 hours has elapsed since you have missed a dose, you can take the dose. If more than 12 hours has elapsed since missing a dose at the normal time, you should not take the dose, but take the next dose at the normal time on the following day. Do not take 2 doses at the same time.

4 Possible side effects

EUROLEN can have side effects.

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

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

- Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of allergic reaction called anaphylactic reaction.
- shortness of breath, chest pain and cough (pulmonary embolism) - especially if additionally taking dexamethasone (a type of corticosteroid medicine used for skin diseases, rheumatic problems, severe allergies or asthma, chronic lung diseases) or erythropoietic medicines (to treat anaemia, a lack of red blood cells).
- tightness or pain in the chest, neck, back or arms, as well as tiredness, light-headedness, abnormal heartbeat and anxiety – all signs of a heart attack.
- Flu-like symptoms that appear first, painful rash that spreads and blisters that follow. Peeling of skin, fever, coughing, itching and sore throat. These signs can be related to Steven Johnson syndrome (SJS), that requires urgent medical attention.
- Flu-like symptoms, cough, runny nose, fever, decreased appetite, redness of skin and detachment of top layer of skin – all signs of Toxic epidermal necrolysis (TEN), a potentially fatal skin reaction.
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting (which may be symptoms of a heart attack/myocardial infarction).
- Respiratory distress.
- Prolonged bleeding, frequent nose bleeds, bruising throughout the body, vomiting of blood, blood in stool or urine (can all be signs of life-threatening acquired haemophilia).

- Severe abdominal pain or tenderness, nausea, vomiting, that can be signs of a ruptured bowel (hole in your intestine).
- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment. Symptoms include nausea, vomiting, diarrhoea, muscle cramps, weakness, tiredness.

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

- leg pain or swelling, as it can be a sign of deep vein thrombosis.
- fever, mouth ulcers, sore throat or susceptibility to infection, that can be signs of neutropenia.
- Medicine-induced allergic reaction. Symptoms include skin eruptions, blood abnormalities, fever and organ complications. Also known as Drug Reaction with eosinophilia (DRESS).
- Stroke. Symptoms include trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg.
- Organ transplant rejection (symptoms may include general discomfort, uneasiness or feeling ill, pain or swelling in the area of the organ, fever, flu-like symptoms).
- Suffering from flu symptoms, that includes coughing with phlegm, fever, chills and difficulty breathing, that can be signs of pneumonia, bronchitis or upper respiratory tract infection.
- Night sweats, fever, unexplained weight loss, tiredness, appetite loss, trouble breathing, pain or swelling in your belly or severe itching. All these can be signs of B-cell lymphomas.

- A fall in the number of white blood cells (the cells that fight infection), platelets (the cells that help the blood to clot, which may lead to bleeding disorders) and red blood cells (anaemia leading to tiredness and weakness).
- High blood sugar levels. Symptoms include increased thirst, headaches, blurred vision, tiredness, frequent urinating, and weight loss.
- Iron overload (symptoms include abdominal pain, arthritic pain, tiredness, abnormal heart rhythm, diabetes, erectile dysfunction).
- Chest pain, shortness of breath especially when lying down (which may be a symptoms of heart failure).
- Leg pain (which could be a symptom of blood clots (thrombosis)).
- Production of much more or much less urine than usual (which may be a symptom of kidney failure).
- Tumour Flare Reaction (TFR), that mimics the disease progression, that includes sudden increase in size and tenderness of disease affected lymph nodes and spleen, a rash and a low-grade fever.
- Sudden, or mild but worsening pain in the upper abdomen and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse − these symptoms may be due to inflammation of the pancreas (pancreatitis - severe cases can be life-threatening).
- Yellowed skin and eyes, stomach pain and swelling, nausea, vomiting, tiredness, dark-coloured urine. All can be signs of liver complications.
- Rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood, that can damage your kidneys). Symptoms include dark, reddish urine, weakness and muscle aches.
- If pregnant, the foetus can suffer from severe life-threatening birth defects.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection of the sinuses that surround the nose.
- Infections of all types.
- Tiredness, cold sensitivity, constipation, dry skin, unexplained weight gain (hypothyroidism).
- Unexpected weight loss, rapid or irregular heartbeat, sweating and irritability (hyperthyroidism).
- Decreased appetite, low levels of potassium in the blood.
- Low levels of calcium, phosphate or magnesium in the blood.
- Dehydration.
- Weight loss.
- Depression or mood change.
- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, taste disturbance, loss of consciousness.
- Blurred vision, cataracts.
- High or low blood pressure.
- Pain, swelling, redness, bleeding from the gums, stomach, or bowels, bruising (haematoma).
- Shortness of breath.
- Bleeding from the nose.
- Diarrhoea, vomiting, nausea, constipation, abdominal pain (including upper), dry mouth, indigestion.
- Toothache.
- Abnormal liver test results.

- Redness of skin, rashes, skin eruptions, skin cracking, flaking, itching, dry skin, increased sweating, dehydration.
- Muscle cramps, muscle aches, bone pain, back pain, joint pain, muscle weakness.
- Fever, swelling of arms, legs and feet, coughing, sinus infection, muscle and body pain, pain or irritation of the throat, headache, chills, tiredness.
- Weight loss.
- Falling.

Less frequent side effects:

- Hypersensitivity (can also be experienced if additionally taking thalidomide, that are used in the treatment of a number of cancers).
- Angioedema (symptoms include hives/ welts that are red, itchy, round or oval shaped, swelling and redness around eyes, cheeks or lips and pain or warmth at affected area).

Frequency is not known:

- General infections, including shingles (painful rash, that may appear as a stripe nor blisters on your upper body).
- Yellowing of eyes, abdominal pain, dark urine (can be signs of hepatitis B infection).
- Dry cough, shortness of breath (that can be signs of interstitial pneumonitis).
- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).
- Inflammation of small blood vessels.
- Second primary malignancies (a new primary cancer, mainly skin cancers).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website or to Eurolab (Pty) Ltd. by email: drug-safety@eurolab.co.za. By reporting side effects, you can help provide more information on the safety of EUROLAB.

5 How to store EUROLEN

- Store all medicines out of reach of children.
- Store at or below 25 °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 **EUROLEN** 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).

Shelf-life

36 months

6 Contents of the pack and other information

What EUROLEN contains

The active substance is lenalidomide.

The other ingredients are: croscarmellose sodium, lactose, magnesium stearate and microcrystalline cellulose.

The 5 mg capsule shells contain FD&C Blue #1 (E133), red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171) and gelatin.

The 10 mg capsule shells contain yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and gelatin.

The 15 mg capsule shells contain black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171) and gelatin.

The 25 mg capsule shells contain titanium dioxide (E171) and gelatin.

Printing ink contains Shellac (E904), propylene glycol (E1520), strong ammonia solution (E527), black iron oxide (E172) and potassium hydroxide (E525).

What EUROLEN looks like and contents of the pack

EUROLEN is packed in PVC/ACLAR/Aluminium blister packs packed in an outer carton.

Each pack of **EUROLEN** contains 3 blister strips of 7 capsules each (Total of 21 capsules per pack).

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

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