Applicant : Eurolab (Pty) Ltd
Proprietary name : Paclitaxel 30 Eurolab & Paclitaxel 100 Eurolab & Paclitaxel 300 Eurolab
Dosage form and strength : Concentrate for solution for infusion 30 mg & 100 mg & 300 mg
Date of submission : 15 September 2022
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APPROVED PATIENT INFORMATION LEAFLET PACLITAXEL EUROLAB

SCHEDULING STATUS: S4

PACLITAXEL 30 EUROLAB, 30,0 mg per 5 ml, concentrate for solution for infusion

PACLITAXEL 100 EUROLAB, 100,0 mg per 16,7 ml, concentrate for solution for infusion

PACLITAXEL 300 EUROLAB, 300,0 mg per 50 ml, concentrate for solution for infusion

Paclitaxel

Sugar free

Read all of this leaflet carefully before you are given PACLITAXEL EUROLAB

- 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.

What is in this leaflet

1. What PACLITAXEL EUROLAB is and what it is used for
2. What you need to know before you use PACLITAXEL EUROLAB
3. How to use PACLITAXEL EUROLAB
4. Possible side effects
5. How to store PACLITAXEL EUROLAB
6. Contents of the pack and other information

1. What PACLITAXEL EUROLAB is and what it is used for

PACLITAXEL EUROLAB belongs to a group of anti-cancer medicines called cytostatic agents. These medicines inhibit the growth of cancer cells.

PACLITAXEL EUROLAB is used for the treatment of cancer. It can be cancer in the ovaries or breast cancer (advanced or spreading), after failure of other standardised prescribed treatment.

PACLITAXEL EUROLAB may also be used for a certain cancer in the lungs (advanced non-small cell lung cancer, NSCLC) in patients who cannot be treated with surgery and/or radiotherapy.

2. What you need to know before you use PACLITAXEL EUROLAB

PACLITAXEL EUROLAB should not be administered to you:

- if you are allergic (hypersensitive) to paclitaxel or to any of the other ingredients of this medicine listed in section 6 especially polyoxyl 35 castor oil;
- if you are pregnant or breastfeeding;
- if you are a child;
- if your number of white blood cells (neutrophils) is too low. This is measured by a doctor or nurse.

If you are unsure about anything, ask your doctor, pharmacist or nurse.

Warnings and precautions

To minimise allergic reactions, you will be given other medicines before you receive PACLITAXEL EUROLAB.

Tell your doctor or healthcare provider before being given the injection:

- if you have heart disease including irregular heartbeats;
- if you have liver problems
- if you have had nerve problems in your hands or in feet, such as numbness, tingling or burning (peripheral neuropathy)
- if you have blood problems, such as changes in the number of some cells e.g. if you have neutropenia (low white blood cell count) or myelosuppression (decreased blood cells)
- if PACLITAXEL EUROLAB is given to you in combination with radiotherapy of the lung
- if PACLITAXEL EUROLAB is given to you in combination with a medicine called cisplatin
- if PACLITAXEL EUROLAB is given to you in combination with a medicine called trastuzumab (used in the treatment of breast cancer)
- if PACLITAXEL EUROLAB was given to you before, and you experienced severe allergic reactions characterised by dyspnoea (shortness of breath), flushing, chest pain and tachycardia (increased heartbeat) and hypotension (low blood pressure) requiring treatment, angioedema (rapid swelling under the skin), and generalised urticaria (rash)
- if PACLITAXEL EUROLAB is given to and you experience high or low blood pressure, and a slow heartbeat (bradycardia)
- if you are unable to take medicines containing alcohol

- if you develop severe or persistent diarrhoea, with fever and stomach pain, during or shortly after the treatment with PACLITAXEL EUROLAB. Your colon could be inflamed (pseudomembranous colitis)

Other medicines and PACLITAXEL EUROLAB

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicine.)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines you have obtained without a prescription.

When used in combination, PACLITAXEL EUROLAB should be given before cisplatin. PACLITAXEL EUROLAB should be given 24 hours after doxorubicin.

Special care should be observed if you are taking medicines which influence the metabolism of paclitaxel such as: ketoconazole (treats fungal infections), erythromycin (antibiotic), fluoxetine (anti-depressant), gemfibrozil (cholesterol medication), rifampicin (TB medication), epilepsy treatment such as carbamazepine, phenytoin, phenobarbital, or HIV treatment such as efavirenz, and nevirapine and for HIV patients receiving protease inhibitors (ritonavir, nelfinavir) as concomitant therapy.

Pregnancy, breastfeeding and fertility

PACLITAXEL EUROLAB may cause harm to the unborn baby. Therefore, you must not become pregnant during treatment with PACLITAXEL EUROLAB and an effective method of contraception should be used whilst receiving treatment and for six months after treatment has finished. Male patients treated with PACLITAXEL EUROLAB are advised not to father a child during and up to six months after treatment.

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 receiving this medicine.

Driving and using machines

This medicine contains alcohol and therefore it may be unwise to drive immediately after a course of treatment. PACLITAXEL EUROLAB may also cause tiredness and dizziness that may affect your ability to drive and use machinery. If you experience these symptoms, do not drive or operate machinery until they have fully resolved.

PACLITAXEL EUROLAB contains polyethoxylated castor oil

PACLITAXEL EUROLAB contains polyethoxylated castor oil that may cause severe allergic reactions. If you are allergic to castor oil, talk to your doctor before you receive PACLITAXEL EUROLAB.

PACLITAXEL EUROLAB contains anhydrous ethanol

PACLITAXEL EUROLAB contains alcohol (ethanol) and this may be harmful for patients suffering from alcoholism and for high risk patients including those with liver problems or epilepsy (fits). The amount of alcohol in this product may alter the effect of other medicines.

3. How to use PACLITAXEL EUROLAB

You will not be expected to give yourself PACLITAXEL EUROLAB. It will be given to you by a person who is qualified to do so.

To minimise allergic reactions, you will be given other medicines before you receive PACLITAXEL EUROLAB. These medicines can be given as either tablets or infusion into a vein or both.
You will receive PACLITAXEL EUROLAB as a drip into one of your veins (by intravenous infusion), through an in-line filter. The healthcare professional will prepare the solution for infusion before it is given to you. The dose you receive will also depend on results of your blood tests. Depending on the type and severity of the cancer you will receive PACLITAXEL EUROLAB either alone or in combination with another anticancer medicine.
PACLITAXEL EUROLAB should always be administered into one of your veins over a period of 3 or 24 hours. It is usually given every 2 or 3 weeks, unless your doctor decides otherwise. Your doctor will inform you about the number of courses of PACLITAXEL EUROLAB you need to receive.

If you are given more PACLITAXEL EUROLAB than you should

Your dose will be carefully calculated by the doctors, so overdose is unlikely. However, if too much is given this is likely to make the usual side effects worse, particularly blood disorders, numbness/tingling especially of the arms, hands, legs or feet, and stomach upsets including vomiting and diarrhoea.
Since a health care provider will administer PACLITAXEL EUROLAB he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PACLITAXEL EUROLAB

Since a health care provider will administer PACLITAXEL EUROLAB, it is unlikely that the dose will be missed.

If you stop using PACLITAXEL EUROLAB

Your doctor will decide when to stop treatment with PACLITAXEL EUROLAB. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

If any of the following happens, tell your doctor immediately:

- Any abnormal bruising, bleeding, or signs of infections such as a sore throat and high temperature.
- Severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.
- Breathlessness and dry cough due to damage to the lung.
- Reaction at the injection site, e.g. local swelling, pain, redness.

These are all very serious side effects. 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:

- Fever, severe chills, sore throat, or mouth ulcers (possible signs of bone marrow suppression)
- Numbness or weakness of the arms and legs (signs of peripheral neuropathy)
- Severe or persistent diarrhoea, with fever and stomach pain.

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:

- An effect on the bone marrow, which can cause decreased numbers of some blood cells. This may cause anaemia. It can also lead to infections, mainly urinary tract and upper respiratory tract infections with reported cases of fatal outcome.

- Decreased number of blood platelets and bleeding.
- Milder allergic (hypersensitivity) reactions, such as flushing and rash.
- Nerve problems affecting the hands and/or feet (peripheral neuropathy), which can cause tingling feelings in the skin, numbness and/or pain.
- Low blood pressure.
- Feeling sick (nausea), being sick (vomiting) and diarrhoea.
- Hair loss.
- Muscle or joint pain.
- Inflammation of areas such as the lining of the mouth.
- Slow heartbeat (pulse).
- Mild changes in nail and skin which soon disappear.
- Painful swelling and inflammation where the injection is given which may cause tissue hardening (occasionally cellulitis, thickening and scarring of the skin (skin fibrosis), death of skin cells (skin necrosis).

Less frequent side effects:

- A state of shock resulting from blood poisoning.
- Serious allergic (hypersensitivity) reactions with e.g. decreased or increased
- Hypersensitivity reactions such as low blood pressure, swelling of the face, difficulty in breathing, skin rash, chills, back pain, chest pain, fast heart beat, abdominal pain, pain in arms and legs, sweating, high blood pressure.
- Serious heart problems like heart muscle degeneration (cardiomyopathy),
- Serious changes in your heart’s rhythm even with fainting. Heart attack.
- Increased blood pressure.
- Blood clot (thrombosis), inflammation of a vein in connection with blood clots.
- Yellowing of the skin (jaundice).
- Pneumonia
- Reduced number of a type of white blood cell with fever (febrile neutropenia)
- Serious allergic (anaphylactic) reaction.
- Effects on the nerves, which can cause muscle weakness in the arms and legs.

- Difficulty in breathing, fluid on the lungs, inflammation of the lungs and other lung problems (lung fibrosis, pulmonary embolism), markedly impaired pulmonary function (respiratory failure).
- Itching, rash and reddened skin.
- Weakness, high temperature (fever), dehydration, oedema, feeling ill.
- Blood poisoning.
- Blockage of the intestines, penetration of the wall of the small intestine or large bowel, inflammation of the lining of the belly (peritoneum), inflammation of the intestine caused by inadequate blood supply, inflammation of the pancreas.
- Increased level of the substance creatinine in the blood
- Acute leukaemia (a type of blood cancer), myelodysplastic syndrome (a diverse collection of blood cell disorders).
- Life threatening allergic reaction (anaphylactic shock).
- Loss of appetite, shock due to decreased blood pressure, cough.
- Effects on the nervous system which can cause paralysis of the intestines (gut) and a decrease in blood pressure when standing up or sitting up from a lying down position, fits (epileptic seizures), cramps, confusion, dizziness, alteration in brain function or structure, headache, loss of the ability to coordinate muscular movement.
- Problems with eyesight and visual disturbances, usually in patients given larger doses.
- Reduction or loss of hearing, ringing in the ears (tinnitus), vertigo.
- Abnormal heart rhythm (atrial fibrillation, supraventricular tachycardia).
- A blood clot in the mesenteric artery, pseudomembranous colitis (an infection of the colon caused by specific bacteria), inflammation of the oesophagus, constipation. Collection of fluid in the abdomen (belly).
- Severe inflammation of the large bowel presenting with fever, watery or bloody diarrhoea, and crampy abdominal pain (neutropenic colitis).
- Dehydration and anorexia.
- Death of liver cells (necrosis of the liver), confusion and other effects (hepatic encephalopathy) caused by changes in the way the liver works (both with reported cases of fatal outcome).

Side effects with an unknown frequency:

- Abnormal blood clotting condition also known as disseminated intravascular coagulation (DIC).

- Constriction of the airway also known as bronchospasm.
- Tumor lysis syndrome (TLS) - a condition that occurs when a large number of cancer cells die within a short period, releasing their contents in to the blood.
- Blurry or wavy vision near or in the center of the field of vision (macular oedema)
- Inflammation (redness, swelling, pain, and heat) of a vein, usually in the legs.
- Redness, swelling, and pain on the palms of the hands and/or the soles of the feet also known as Hand-foot syndrome.
- SLE (systemic lupus erythematosus) - a chronic inflammatory condition caused by an autoimmune disease.
- Scleroderma - autoimmune disease causing the skin to gradually tighten, thicken or harden.

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. 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 PACLITAXEL EUROLAB.

5. How to store PACLITAXEL EUROLAB

Store all medicines out of reach of children.

Store at or below 25 °C. To be kept in outer container until required. Protect from light.

Discard any unused portion.

Do not refrigerate.

Store in original package.

Do not use after the expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PACLITAXEL EUROLAB contains

- The active substance is paclitaxel.

- The other ingredients are polyoxyl 35 castor oil 527,0 mg/ml and anhydrous ethanol 391 mg/ml.

What PACLITAXEL EUROLAB looks like and contents of the pack

PACLITAXEL EUROLAB is a clear, colourless to slightly yellow solution, free from visible evidence of contamination.

PACLITAXEL EUROLAB is available as:

- **PACLITAXEL 30 EUROLAB:** 5 ml filled in a 5 ml or 6 ml clear glass vial with an omniflex rubber stopper sealed with an aluminium seal and red coloured flip off top.
- **PACLITAXEL 100 EUROLAB:** 16,7 ml filled in a 20 ml clear glass vial with an omniflex rubber stopper sealed with an aluminium seal and red coloured flip off top.
- **PACLITAXEL 300 EUROLAB:** 50 ml filled in a 50 ml clear glass vial with an omniflex rubber stopper sealed with an aluminium seal and red coloured flip off top.

Holder of Certificate of Registration

Eurolab (Pty) Ltd

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