Applicant : Eurolab (Pty) Ltd
Proprietary name : Eurotax 20 mg & 80 mg & 140 mg
Dosage form and strength : Concentrate for solution for infusion 20 mg & 80 mg & 140 mg
Date of submission : 01 April 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EUROTAX 20 mg Concentrate for solution for infusion

EUROTAX 80 mg Concentrate for solution for infusion

EUROTAX 140 mg Concentrate for solution for infusion

(Docetaxel)

Sugar free

Read all of this leaflet carefully before you are given EUROTAX

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

1. What EUROTAX is and what it is used for

EUROTAX is an anticancer medicine that contains docetaxel. Docetaxel is used to treat breast cancer, non-small cell lung cancer (NSCLC), ovarian cancer, prostate cancer and head and neck cancer or the palliative treatment of gastric cancer. EUROTAX is used as a single medicine in some cases but can be combined with other anticancer medicines in the

treatment of the specific cancer. The doctor will decide what the most appropriate treatment will be for you.

2. What you need to know before you use EUROTAX

EUROTAX should not be administered to you:

- If you are hypersensitive (allergic) to docetaxel or polysorbate 80 or any of the other ingredients of EUROTAX (listed in section 6).
- If you are pregnant or breastfeeding your baby (see under this section 2 - Pregnancy, lactation and fertility)
- if you have a baseline neutrophil count of <1500 cells/mm3 (white blood cells low). This will be determined by doing a blood test before your scheduled treatment.
- if you have severe liver impairment.
- The safe use of EUROTAX in children has not been established.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have ever suffered an allergic reaction to docetaxel-containing medicines.

  You will be closely monitored for allergic reactions, especially during the first and second infusions. An allergic reaction can occur within a few minutes following the start of the therapy. If you experience minor symptoms such as reddening or reactions at the infusion site, interruption of your therapy is not required. However, if you experience more severe side-effects, such as low blood pressure, constriction of the air passages or a generalised rash, you will be symptomatically treated.
- If you have abnormal liver function or liver impairment or any abnormalities with regards to the liver enzymes.
- If you have kidney problems or high levels of uric acid in your blood.

- If you experience water retention such as fluid that accumulates around your lungs, fluid around the heart or abdominal fluid.
- If you experience any respiratory problems or difficulty in breathing.
- If you experience a localised skin redness of the extremities (palms of your hands and soles of your feet) with water retention followed by skin peeling. This type of toxicity can lead to the interruption or discontinuation of your treatment.
- If you develop severe peripheral neurotoxicity (weakness, numbness and pain from nerve damage, usually in the hands and feet) including paraesthesia ("pins-and-needles" sensation), dysaesthesia (abnormal, unpleasant sensation when touched, caused by damage to nerves) and pain that requires a reduction of your dose.
- If you experience an irregular or too fast heartbeat, or you experience dizziness, shortness of breath, light-headedness, heart palpitations, chest pain or seizures, that can all be signs or symptoms of ventricular tachycardia.
- If you experience water retention, swelling, breathing difficulty, as well as swollen abdomen that can all be signs of congestive heart failure.
- If you experience blurred or a decrease in vision.
- If you experience any abdominal/ stomach pain and tenderness, fever or diarrhoea, as this can be symptoms of serious gastrointestinal toxicity.
- If you experience chronic tiredness, shortness of breath, chilled sensation, sometimes chest pain, chronic infections, bruise or bleed easily, that can be signs of leukemia (group of blood cancers).

Your doctor will do frequent blood cell counts in order to monitor the occurrence of neutropenia (which can cause severe infections).

If you are older than 60 years of age, your doctor will carefully monitor you, to ensure that you don't develop any serious side-effects.

Your doctor may prescribe you a pre-medication consisting of a corticosteroid such as dexamethasone, that you should start taking 1-day prior to your treatment with EUROTAX. The pre-medication may reduce any side-effects that EUROTAX may cause.

Contraceptive measures must be taken during and for the minimum of three months after treatment with EUROTAX.

EUROTAX contains ethanol

EUROTAX 20 mg

This medicine contains ethanol, equivalent to 10 ml of beer or 4 ml of wine.

Harmful if you are suffering from alcoholism.
You need to take into account if you are pregnant or breastfeeding and in a high-risk group, such as suffering from liver disease, or epilepsy.

EUROTAX 80 mg

This medicine contains ethanol, equivalent to 40 ml of beer or 16 ml of wine.

Harmful if you are suffering from alcoholism.
You need to take into account if you are pregnant or breastfeeding and in a high-risk group, such as suffering from liver disease, or epilepsy.

EUROTAX 140 mg

This medicine contains ethanol, equivalent to 70 ml of beer or 28 ml of wine.

Harmful if you are suffering from alcoholism.

You need to take into account if you are pregnant or breastfeeding and in a high-risk group, such as suffering from liver disease, or epilepsy.

EUROTAX contains 400 mg ethanol (alcohol) per ml concentrate.

EUROTAX is harmful if you are suffering from alcoholism. If you are pregnant or breastfeeding or in a high-risk group for example suffering from liver disease or epilepsy, the alcohol content needs to be taken into account.

In higher doses the amount of alcohol may alter the effects of other medicines you are using and may impair your ability to drive or use machines (see section below "**Driving and using machines**").

Other medicines and EUROTAX

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

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following:

- Ciclosporin (an immunosuppressant medication for rheumatoid arthritis, psoriasis, Chron's disease, nephrotic syndrome and in organ transplants).
- Erythromycin, clarithromycin, troleandomycin, or telithromycin (an antibiotic used to treat bacterial infection).
- Ketoconazole, itraconazole or voriconazole (an antifungal used to treat fungal infections).
- Indinavir, nelfinavir, ritonavir, saquinavir (used to treat human immunodeficiency virus (HIV) infections).

The amount of alcohol in EUROTAX may alter the effects of other medicines.

EUROTAX with food, drink and alcohol

EUROTAX will be given by slow injection into one of your veins (an intravenous infusion) and will therefore not be affected by food or drink.

You should not consume alcohol before or after given EUROTAX, as EUROTAX already contains alcohol (ethanol), that may result in an overdose (see section above "**EUROTAX contains ethanol**").

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding or 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 EUROTAX.

Your doctor will not administer EUROTAX to you as the use of EUROTAX in pregnancy is contraindicated. It is not recommended that you become pregnant while receiving treatment with EUROTAX.

You must not breastfeed your baby when you are receiving treatment with EUROTAX.

Docetaxel is destructive to cells and may change the fertility in men. Therefore, if you are male and treated with EUROTAX, you are advised not to father a child during and up to 6 months after treatment and to seek advice on preserving sperm prior to treatment.

Driving and using machines

EUROTAX contains alcohol which may impair your ability to drive or use machines.

It is not always possible to predict how EUROTAX may interfere with your daily activities. You should not drive, use machines or equipment, until you are aware of how EUROTAX affects you.

EUROTAX contains ethanol (alcohol).

EUROTAX contains alcohol (ethanol (anhydrous)) – see section 6. Tell your doctor if you have a history of drug or alcohol abuse or addiction.

How to use EUROTAX

Do not share medicines prescribed for you with any other person. The dose of EUROTAX is based on your body surface area (calculated from your height and weight). The dose will also depend on the results of blood tests and whether you have previously experienced side effects with EUROTAX.

EUROTAX is administered as a one-hour infusion every 3-weeks. The usual dose of EUROTAX is 75 mg/m^2, but it will depend on your condition and what other treatments you will receive.

Method and route of administration

- EUROTAX will be prescribed for you by a specialist in cancer treatment.
- You will be treated by a healthcare professional, who will have made up the required dose of EUROTAX.
- EUROTAX is given by slow injection into one of your veins (an intravenous infusion) over a 1-hour period.
- EUROTAX will be given to you at the same time as other medicines.
- The needle must remain in the vein while the EUROTAX is being given. If the needle comes out or becomes loose, or the solution is going into the tissue surrounding the vein, you may feel discomfort or pain. Tell the nurse or doctor immediately.

Frequency of administration

You should usually receive your infusion once every three weeks.

Duration of treatment

The duration of the treatment will be determined by your doctor.

If you receive more EUROTAX than you should

As this medicine is administered by a healthcare professional, it is highly unlikely that you will be given too much or too little.

In case of overdose, you may experience increased side effects. Your doctor may give you appropriate treatment for these side effects.

If you have any further questions on the use of this medicine, ask your healthcare professional.

3. Possible side effects

EUROTAX can have side effects.

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

The most frequently reported adverse reactions of docetaxel alone are: decrease in the number of red blood cells or white blood cells, hair loss, nausea, vomiting, sores in the mouth, diarrhoea and tiredness.

The severity of adverse events of docetaxel may be increased when docetaxel is given in combination with other chemotherapeutic medicines. During the infusion at the hospital the following allergic reactions may occur:

- flushing, skin reactions, itching
- chest tightness; difficulty in breathing
- fever
- back pain
- low blood pressure.

More severe reactions may occur.

If you had an allergic reaction to paclitaxel, you may also experience an allergic reaction to docetaxel, which may be more severe.

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

- sepsis (symptoms include fever, low body temperature, rapid breathing, a fast heart rate and confusion). Early signs include a rapid heart rate, decreased urination, and high blood sugar).
- pneumonia (symptoms that can present are a productive cough, fever accompanied by shaking chills, shortness of breath, sharp or stabbing chest pain during deep breaths, and an increased rate of breathing, that can be fatal).
- fever, often with other signs of infection: if this happens you must tell your doctor immediately, as this can be signs of febrile neutropenia.
- heart failure (symptoms include chest pain, cough, dizziness, tiredness, loss of appetite, fast breathing, shortness of breath, bloating or water retention, excess urination at night, heart palpitations).

These are all very serious side effects. If you have them, you may have had a serious reaction to EUROTAX. You may need urgent medical attention or hospitalisation.

Frequent:

- infections, oral fungal infection.
- neutropenia (decrease in number of white blood cells) accompanied with infection.
- Cancer pain.
- fever, painful swallowing, pain of the gums, skin abscesses, and ear infection, all signs of neutropenia.

- decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection) and platelets.
- nosebleeds, and/or bleeding gums, bruising. Some women may have heavier or longer periods or breakthrough bleeding (thrombocytopenia).
- allergic reactions as described above.
- loss of appetite (anorexia).
- decreased appetite, dehydration.
- tingling and numbness, pins and needles and hypersensitivity, increased pain or inability to feel pain, loss of ability to detect changes in heat and cold, loss of co-ordination, burning or stabbing pains (peripheral sensory neuropathy).
- impaired balance and coordination or, most commonly, muscle weakness (peripheral motor neuropathy).
- alteration in sense of taste (dysgeusia).
- alteration in sense of smell (parosmia).
- pins and needles (paraesthesia), dizziness, headache.
- increased tearing of the eyes (increased lacrimation).
- inflammation or infection of the eye (conjunctivitis).
- loss of hearing.
- irregular heartbeat.
- myocardial ischemia (symptoms include chest pain, indigestion, nausea, light-headedness, sweating, fast heart rate, shortness of breath).
- low or high blood pressure.
- abnormal bleeding from nose or mouth.
- hot flush.
- Inflammation of a vein.
- vein disorder.

- shortness of breath.
- cough
- throat pain, cough, nosebleed (epistaxis).
- inflammation of the mouth and lips (stomatitis).
- pain or irritation in the throat that can occur with or without swelling, often accompanies infections, such as a cold or flu.
- upset stomach, including nausea, vomiting and diarrhoea, constipation, indigestion, abdominal pain, abdominal pain upper, dry mouth, gastrointestinal bleeding.
- Difficulty or painful swallowing (dysphagia/ odynophagia).
- hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed.
- skin reactions.
- nail disorders.
- redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel (this may also occur on the arms, face, or body).
- Dermatitis (symptoms include itchy dry skin or a rash, flakiness, bumps, fissures, peeling or redness).
- Skin redness (rash erythematous).
- Exfoliative (scaly or flaky) rash.
- Nail discolouration, nail detachment (onycholysis).
- Itchy rash, dry skin.
- Skin peeling (desquamation).
- muscle pain (can be severe), joint pain.
- Pain in legs and arms, back pain.
- Absence of monthly menstrual periods.

- fluid retention (can be severe), tiredness, weakness (asthenia), pain, fever (pyrexia), infusion site reaction, chest pain (not heart-related).
- fluid accumulation causing swelling, especially in lower limbs (oedema peripheral).
- increase in blood bilirubin, that is a product that forms after breakdown of your red blood cells (symptoms include abdominal pain or swelling, chills, fever, chest pain, weakness, light-headedness, tiredness, nausea, vomiting, dark urine).
- Passing little or no urine (abnormal kidney function)
- Increased blood alkaline phosphatase, AST or ALT (type of liver enzymes) (symptoms include weakness, tiredness, loss of appetite, nausea, vomiting, abdominal swelling, yellow eyes and skin, dark urine, itching).
- weight gain or loss.

Less frequent:

- loss of consciousness (syncope).
- paralysis or weakness of limbs, altered sensation, tingling and numbness in limbs, headache, vision loss, loss of memory, behavioural problems, all signs of neurotoxicity.
- excess sleepiness (somnolence).
- swelling in arm or leg, caused my lymphatic system blockage (lymphoedema).
- ulcers or inflammation in the stomach, small intestine or colon; intestinal perforation – symptoms may include vomiting blood, bleeding from the back passage (rectum) or bloody or severe diarrhoea.
- sudden swelling of the leg/arm which may be due to blood clots.
- acute myeloid leukaemia and myelodysplastic syndrome (types of blood cancer), may occur (when EUROTAX is used together with certain other anticancer treatments).

Frequency unknown:

- Severe skin problems such as:

- Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN). Symptoms may include blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.
- Acute generalised exanthematous pustulosis (AGEP). Symptoms may include a red, scaly, widespread rash with bumps under the skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever.

- Tumour lysis syndrome which may manifest as pain in your side, seizures, or a reduced amount or darkening of urine. This can cause life-threatening kidney failure and heart problems.
- Myositis (inflammation of the muscles (hot, red and swollen muscles) which produces muscle pain and weakness).
- Interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing)
- Pneumonia (infection of the lungs)
- Pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath)
- Blurred vision due to swelling of the retina within the eye (cystoid macular oedema)
- Decrease of the sodium, potassium, magnesium and/or calcium in your blood (electrolyte balance disorders)
- Non-Hodgkin lymphoma (a cancer affecting the immune system), renal cancer and other cancers (when EUROTAX is used together with certain other anticancer treatments).

These are very serious side effects. You may need urgent medical attention or hospitalisation.
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 or pharmacist or nurse. 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 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 EUROTAX.

4. How to store EUROTAX

Store all medicines out of reach of children.

Store at or below 25 °C, in the original packaging, protected from light. Do not refrigerate or freeze.

Keep the vial in the outer carton until required for use.

Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Once added as recommended into the infusion bag, the EUROTAX infusion solution, if stored at or below 25 °C, in non-PVC bags, is stable for 8 hours. It should be used within 8 hours (including the one-hour infusion intravenous administration).

In addition, physical and chemical in-use stability of the infusion solution prepared as recommended has been demonstrated for 3 days when stored between 2 to 8 °C.

5. Contents of the pack and other information

What EUROTAX contains

The active substance in EUROTAX is docetaxel trihydrate equivalent to docetaxel (anhydrous). Each ml of solution contains 20 milligrams docetaxel.

The other ingredients are Citric acid (anhydrous), Ethanol (cosolvent for docetaxel and solvent for Kollidon 12PF and citric acid), Kollidon 12 PF (solubility enhancer), Nitrogen (inert gas used for solution filtration) and Polysorbate 80 (solvent for docetaxel).

What EUROTAX looks like and contents of the pack

EUROTAX 20 mg/1 ml: One 5 ml colourless glass vial with a grey rubber stopper and an aluminium flip off cap.

The vial can be with or without overwrapping/sleeving, included or not in a thermoformed tray, packed in a carton box.

EUROTAX 80 mg/4 ml: One 8 ml or 10 ml colourless glass vial with a grey rubber stopper and an aluminium flip off cap.

The vial can be with or without overwrapping/sleeving, included or not in a thermoformed tray, packed in a carton box.

EUROTAX 140 mg/7 ml: One 11 ml or 10 ml colourless glass vial with a grey rubber stopper and an aluminium flip off cap.

The vial can be with or without overwrapping/sleeving, included or not in a thermoformed tray, packed in a carton box.

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

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EUROTAX 140: 52/26/0265

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