PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before ERIOX intravenous infusion is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine is to be administered only by or under the immediate supervision of your doctor.

Scheduling Status:

ERIOX 20 / ERIOX 80: S4

ERIOX 20 / ERIOX 80 Diluent: S2

Proprietary name, Strength and Pharmaceutical Form:

ERIOX 20 (each vial contains 20 mg docetaxel anhydrous).

ERIOX 20 Diluent: Each vial contains 1,5 ml anhydrous ethanol and water for injection.

ERIOX 80 (each vial contains 80 mg docetaxel anhydrous).

ERIOX 80 Diluent: Each vial contains 6 ml anhydrous ethanol and water for injection.

1. WHAT ERIOX CONTAINS

Active ingredient: Docetaxel anhydrous.

Inactive ingredients: Polysorbate 80, anhydrous ethanol and water for injection.

2. WHAT ERIOX IS USED FOR

ERIOX belongs to a general group of medicines known as antineoplastics. It is used to treat certain kinds of cancer.

Before you begin treatment with ERIOX, you and your doctor should discuss the advantages of this medicine as well as the risks of using it. ERIOX should be administered under direct physician supervision.

3. BEFORE YOU TAKE ERIOX

Do not take ERIOX:

- If you are allergic to docetaxel, paclitaxel or polysorbate 80.
- Patients with baseline neutrophil count of < 1500 cells/mm^3.
- Tell your doctor if you are pregnant of if you intend to have children. This medicine may cause birth defects if either the male or female is receiving it at the time of conception, or if it is taken during pregnancy.
- Tell your doctor if you are breast-feeding of if you intend to breast-feed during treatment with this medicine. Because ERIOX may cause serious side-effects in nursing babies, breast-feeding is not recommended while you are receiving this medicine.
- Safety and efficacy in children have not been established.
- ERIOX should not be used if you are suffering from severe liver dysfunction.

Take special care with ERIOX:

It is very important that your doctor check your progress at regular visits to make sure that ERIOX is working properly and to check for unwanted effects.

While you are being treated with ERIOX, and after you stop treatment with it, do not have any immunizations (vaccinations) without your doctor's approval. Docetaxel may lower your

body's resistance and there is a chance you might get the infection the immunization is meant to prevent

ERIOX can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection.

Pregnancy and breastfeeding:

Do not use **ERIOX** if you are pregnant, planning to become pregnant or breastfeeding.

Driving and using machinery:

ERIOX has no effect on the ability to drive or operate machinery.

Using other medicines with ERIOX:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ERIOX** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Inform your doctor if you are currently being treated with any of the following

- Bone marrow suppressants or radiotherapy
- Erythromycin, ketoconazole, midazolam, orphenadrine, testosterone and troleandomycin.
- Immunosuppressants (e.g. azathioprine, chlorambucil, corticosteroids, cyclophosphamide, cyclosporine, mercaptopurine, muromonab CD-3 and tacrolimus)

4. HOW TO USE ERIOX

Your doctor will determine the dose that is suitable for you condition. You will receive the medication through infusion into a vein.

If you take more ERIOX than you should:

This product is administered under doctor's supervision. You will be constantly monitored for symptoms and signs of an overdosage.

If you forget to take ERIOX:

This product is administered under your doctor's supervision.

5. POSSIBLE SIDE EFFECTS

ERIOX may have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor.

The following side-effects indicate the need for medical attention:

Frequent occurrence

- Unusual tiredness or weakness
- Fever
- Swelling of fingers, hands feet, or lower legs

Less frequent occurrence

- Allergic reaction (cough, difficulty swallowing, fast heartbeat, dizziness, hives and itching, shortness of breath)
- Red, scaly, swollen or peeling areas of skin

- Shortness of breath; fever with or without chills

Medical attention is required for the following side-effects only if they continue or become bothersome:

Frequent occurrence

- Skin rash or redness
- Nausea, diarrhoea
- Sores or ulcers on lips or tongue or inside the mouth

Less frequent occurrence

- Pain in joints or muscles
- Cough; bloody nose; unusual tiredness or weakness
- Headache; vomiting
- Irritation, swelling or pain at the injection site

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ERIOX

- Unopened vials should be stored between 2°C and 8°C, protected from light. Freezing does not adversely affect the product.
- The **ERIOX** premix solution (10mg docetaxel *I* ml) is stable for 8 hours in a refrigerator or at room temperature.
- The **ERIOX** infusion solution must be administered as soon as possible after preparation. Discard any unused solution.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use after the expiry date printed on the vial.

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

7. PRESENTATION OF ERIOX

ERIOX 20: Transparent glass type I vials of 6 ml with a 20 mm Teflon-chlorobutyl stopper, aluminium crimp cap and aqua safety flip-off.

ERIOX 20 Diluent: Transparent glass type I vials of 6 ml with a 20 mm Teflon-chlorobutyl stopper, aluminium crimp cap and blue safety flip-off.

ERIOX 80: Transparent glass type I vials of 15 ml with a 20 mm Teflon-chlorobutyl stopper, aluminium crimp cap and aqua safety flip-off.

ERIOX 80 Diluent: Transparent glass type I vials of 15 ml with a 20 mm Teflon-chlorobutyl stopper, aluminium crimp cap and blue safety flip-off.

8. IDENTIFICATION OF ERIOX

ERIOX 20 and **ERIOX 80:** Clear, oily, yellow or brown-yellow solution essentially free from particulate matter. The diluted solution is a clear, yellow solution.

ERIOX 20 Diluent and **ERIOX 80 Diluent:** Colourless, clear solution, essentially free of particulate matter.

9. REGISTRATION NUMBERS

ERIOX 20: 42/26/0006

ERIOX 20 Diluent: 42/34/0007

ERIOX 80: 42/26/0008

ERIOX 80 Diluent: 42/34/0009

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Eurolab (Pty) Ltd.

Woodmead Office Park,

3 Stirrup Lane, Van Reenens Avenue,

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11. DATE OF PUBLICATION

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