Teva Pharmaceuticals (Pty) Ltd
Product name: Eposin
Dosage form and strength: Concentrate for Infusion (20 mg/ml)
Registration Number: 32/26/0263

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

EPOSIN concentrate for infusion, 20 mg/ml of etoposide.

Etoposide

Contains ethanol 243 mg/ml

Preservative*: Benzyl alcohol 3 % *m/v

Read all of this leaflet carefully before you are given EPOSIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- EPOSIN 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 EPOSIN IS AND WHAT IT IS USED FOR:

EPOSIN belongs to the group of medicines derived from podophyllotoxin. It is used to treat testicular and certain types of lung cancers.

EPOSIN is available only with your doctor's prescription.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EPOSIN:

EPOSIN should not be administered to you:

Before you begin treatment with EPOSIN, you and your doctor should talk about the good EPOSIN will do as well as the risk of using it.

- if you are allergic to etoposide or any of the other ingredients in the formulation. Tell your doctor and pharmacist if you are allergic to any other substances, such as foods, preservatives, or dyes (listed in **section 6**)
- if you have chickenpox, existing or recent (including recent exposure) or shingles
- if you suffer from kidney or liver problems
- if you have a weak immune system (from disease or from treatment with other cancer medicines)
- if you have decreased ability or inability of the bone marrow to make white blood cells, red blood cells, and platelets
- if you have a weak immune system and you are being vaccinated against yellow fever at the same time
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

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

Take special care with EPOSIN:

- if you have had radiotherapy or chemotherapy recently

- EPOSIN can lower the blood cells that help your body fight infections. This can make it easier for you to bleed from an injury or get sick from being around others who are ill
- acute leukaemia can occur after the treatment of EPOSIN
- make sure you tell your doctor of any other medical problems especially if you have had an infection recently. Your blood will need to be tested on a regular basis to ensure your blood cells do not get too low
- tell your doctor if you have allergic reactions such as low blood pressure, irregular heartbeat, difficulty in breathing, chills, fever, flushing
- tell your doctor or nurse right away if you notice any reactions at the injection site, as the infusion might need to be stopped.
- if you have low levels of a protein called albumin in your blood.
- tell your doctor if you have problems with your liver.
- tell your doctor if you have problems with your kidney.

If you have reduced liver or kidney function, your doctor may also want you to take regular blood tests to monitor these levels.

Children and adolescents:

Safety and efficacy in paediatric patients have not been established.

Other medicines and EPOSIN:

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

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary.

Tell your doctor or pharmacist if you are using other medicines such as:

- the immunosuppressant ciclosporin (often given after an organ transplant) may increase the effect of EPOSIN
- cisplatin (used to treat cancer), as it may increase the effect of EPOSIN
- myelosuppressive (inhibiting bone marrow activity) medicines, as these may increase the effect of EPOSIN
- the blood clotting effect of anti-coagulants such as warfarin which are used to thin the blood may be reduced
- medicines for epilepsy such as phenytoin can reduce efficacy of EPOSIN
- the analgesic (used for pain) and fever lowering medicines phenylbutazone, aspirin and aspirin related medicines (sodium salicylate) may increase the effect of EPOSIN
- vaccines for yellow fever or other live vaccines should not be given during treatment with EPOSIN.

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 healthcare provider for advice before receiving EPOSIN.

EPOSIN must not be used during pregnancy (see **section 2 WHAT YOU NEED TO KNOW BEFORE YOU USE EPOSIN**).

Tell your doctor if you are pregnant or if you intend to have children as EPOSIN may cause foetal harm when administered during pregnancy. Be sure that you have discussed this with your doctor before receiving EPOSIN. Effective birth control to prevent pregnancy is advised during EPOSIN treatment and after the end of EPOSIN treatment for the following 6 months for women and for 3 months for men. It is advised that women of childbearing age should be advised not to fall pregnant while receiving EPOSIN. Tell your doctor right away if you think you have become pregnant while receiving EPOSIN.

Men should not father a child whilst being treated with EPOSIN and until [~~6~~]3 months after treatment has finished. It is advised for men to consider sperm preservation before treatment with EPOSIN, because infertility after treatment can occur.

You must not breastfeed while you are receiving EPOSIN.

Tell your doctor if you are breastfeeding or if you intend to breastfeed during treatment with EPOSIN, because EPOSIN may cause serious side effects.

Driving and using machines:

No studies on the effects on the ability to drive and use machines have been performed.

However, if you feel tired, sleepy, nauseous, dizzy, or have vision disturbance, you should not drive or operate any machinery before you know how EPOSIN affects you.

It is not always possible to predict to what extent EPOSIN may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which EPOSIN affects you.

EPOSIN contains ethanol and benzyl alcohol:

EPOSIN contains 24,3 vol % ethanol (alcohol), i.e. up to 1 215 mg per dose, equivalent to 30 ml beer, 10 ml wine per dose.

Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

EPOSIN contains 150 mg benzyl alcohol in 5 ml unit which is equivalent to 30 mg/ml.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called 'gasping syndrome') in young children.

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called 'metabolic acidosis').

3. HOW TO USE EPOSIN:

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

Safety and efficacy in paediatric patients have not been established.

EPOSIN should be administered under the supervision of a doctor experienced in the use of cancer chemotherapeutic medicines. Severe bone marrow suppression may occur, complicated by bleeding or infection, which may be fatal.

Your medicine will be given to you by injection into a vein under the direction of your doctor. Your doctor will decide what dose to give and number of days treatment you will receive depending on your condition.

The amount of EPOSIN you will receive depends on many factors, including your height and weight, your general health or other health problems, and the type of cancer you have.

Your doctor will determine your exact dosage and schedule.

If you receive more EPOSIN than you should:

Since a healthcare provider will administer EPOSIN he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use EPOSIN:

Since a healthcare provider will administer EPOSIN, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

EPOSIN can have side effects.

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

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

- shortness of breath with tightness of the chest
- swelling of your face, lips, tongue or throat
- itchy rash and fever
- skin rashes that cause blistering (this can affect the mouth and tongue). These may be signs of a condition known as Stevens-Johnson Syndrome, or toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to EPOSIN. 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, chills, body aches, flu symptoms
- white patches or sores inside your mouth or on your lips
- easy bruising or bleeding
- unusual weakness
- fast heart rate
- severe nausea and vomiting
- feeling light-headed, fainting

- loss of appetite.

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

The following side effects may occur frequently:

- infection (including infections seen in patients with a weakened immune system, e.g., a lung infection called pneumocystis jirovecii pneumonia)
- blood disorders (this is why you will be having blood tests between courses of treatment)
- acute severe blood cancer (leukaemia)
- decreased production of blood cells and platelets (myelosuppression)
- mild nausea, vomiting, stomach pain
- diarrhoea, constipation
- sore lips, mouth or throat ulcers
- acid reflux
- increased liver enzymes
- damage to the liver (hepatotoxicity)
- mild itching or skin rash
- temporary hair loss
- sleepiness or tiredness (somnolence)
- tingling or numbness in hands and feet
- generally feeling unwell
- irregular heartbeat (dysrhythmia), or a heart attack (myocardial infarction)
- high or low blood pressure
- changes in skin colour (pigmentation)
- inflammation of a vein

- leakage of the medicine into the surrounding tissues (extravasation) with symptoms such as pain, irritation and swelling
- lack of energy (asthenia)

The following side effects may occur less frequently:

- convulsions (seizures)
- temporary blindness (transient cortical blindness)
- bleeding
- pulmonary fibrosis (scarring throughout the lungs)
- interstitial pneumonitis (lung inflammation)
- a change in the way things taste (dysgeusia)
- difficulty swallowing (dysphagia)
- a sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (radiation recall dermatitis).

Side-effects that occur with unknown frequency:

- swelling in the arms and legs
- severe liver, kidney or heart damage from a condition called tumour lysis syndrome, caused by harmful amounts of substances from the cancer cells getting into the blood stream, has been seen sometimes when EPOSIN is taken along with other medicines used to treat cancer
- inflammation of the optic nerve
- difficulty breathing
- acute renal failure
- infertility.

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 EPOSIN.

5. HOW TO USE EPOSIN:

Store at or below 25 °C and protect from light. Do not freeze.

After dilution to a concentration of 0,2 mg/ml or 0,4 mg/ml etoposide, the resulting solution is stable for respectively 96 and 24 hours at room temperature under normal light conditions.

Store all medicines out of reach of children.

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 EPOSIN contains:

Active ingredient: Each ml contains 20 mg etoposide.

Inactive ingredients for concentrate for infusion: Benzyl alcohol, citric acid, ethanol dehydrated, polyethylene glycol 300, polysorbate 80.

What EPOSIN look like and contents of the pack:

EPOSIN is a clear, yellowish viscous solution.

100 mg/5 ml: Packed into 10 ml colourless glass vials covered with a transparent sleeve and with chlorobutyl rubber stoppers, aluminium seals and snap-on caps. Each vial is packed in an outer carton.

Holder of Certificate of Registration:

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This leaflet was last revised in:

22 April 2024

Registration number:

32/26/0263