

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ETOPOSIDE-HEXAL solution for infusion 50 mg/2,5 ml

ETOPOSIDE-HEXAL solution for infusion 100 mg/5 ml

ETOPOSIDE-HEXAL solution for infusion 200 mg/10 ml

ETOPOSIDE-HEXAL solution for infusion 400 mg/20 ml

ETOPOSIDE-HEXAL solution for infusion 1000 mg/50 ml

### Read all of this leaflet carefully before you start using ETOPOSIDE-HEXAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ETOPOSIDE-HEXAL 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.

### 1. WHAT ETOPOSIDE-HEXAL CONTAINS

The active substance is etoposide.

Each ETOPOSIDE-HEXAL vial contains 20 mg etoposide per 1 ml of solution.

The other ingredients are anhydrous citric acid, benzyl alcohol (2 % m/v), ethanol 96 %, macrogol 300 and polysorbate 80

### 2. WHAT ETOPOSIDE-HEXAL IS USED FOR

ETOPOSIDE-HEXAL is used in the treatment of various types of tumours including testicular tumours and lung tumours.

### **3. BEFORE YOU USE ETOPOSIDE-HEXAL**

#### **Do not receive ETOPOSIDE-HEXAL:**

- If you are hypersensitive (allergic) to etoposide or any of the other ingredients of ETOPOSIDE-HEXAL (see “WHAT ETOPOSIDE-HEXAL CONTAINS”).
- If you have a weak immune system and you are being vaccinated against yellow fever at the same time, or receiving other live vaccines.
- If you are pregnant or breastfeeding.

#### **Take special care with ETOPOSIDE-HEXAL:**

- ETOPOSIDE-HEXAL should only be administered under the supervision of a doctor with experience in cancer treatment medication. Some side effects may require immediate attention by the doctor.
- If you have a bone marrow disorder. Your doctor will observe for bone marrow depression regularly during and after treatment with ETOPOSIDE-HEXAL.
- Before the start of therapy, during the therapy, and before each course of treatment, your blood should be tested (white blood cells, platelets, haemoglobin), kidney and liver function checked, and neurological functions should be investigated.
- If you have received other anticancer treatment or radiotherapy, your doctor should check the number of blood cell in your blood before treatment starts.
- Acute leukaemia can occur after the treatment of ETOPOSIDE-HEXAL.
- If you experience an allergic reaction with chills, fever, rapid heartbeat, difficulty breathing, tightening of the chest and low blood pressure. Tell your doctor immediately.
- If you have low serum albumin levels, you may have an increased risk for toxicities.
- If you have a bacterial infection, it should be treated before ETOPOSIDE-HEXAL is given.
- Safety and efficacy in children has not been systematically studied. Therefore ETOPOSIDE-HEXAL is not recommended for use in this age group.

#### **Receiving ETOPOSIDE-HEXAL with food and drink:**

ETOPOSIDE-HEXAL is not affected by food or drink.

**Pregnancy and Breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before receiving ETOPOSIDE-HEXAL.

ETOPOSIDE-HEXAL can cause malformation of embryo or foetus. Therefore ETOPOSIDE-HEXAL should not normally be administered to pregnant women. If used during pregnancy, the patient must be aware of the potential risk to the foetus.

Do not use ETOPOSIDE-HEXAL if you are breastfeeding.

Women of child bearing age must avoid pregnancy and take effective contraceptive measures during treatment and until at the earliest 6 months after therapy with ETOPOSIDE-HEXAL. Men should not father a child whilst being treated with ETOPOSIDE-HEXAL and until 6 months after treatment has finished. It is advised for men to consider sperm preservation before treatment with ETOPOSIDE-HEXAL, because infertility after treatment can occur.

**Driving and using machinery:**

ETOPOSIDE-HEXAL can cause tiredness and sleepiness and this may impair the ability to drive and use machines.

**Important information about some of the ingredients of ETOPOSIDE-HEXAL:**

ETOPOSIDE-HEXAL contains ethanol (alcohol). This may be dangerous for patients suffering from alcoholism and for patients in high-risk groups such as those with liver problems or epilepsy (fits). The amount of alcohol in ETOPOSIDE-HEXAL may alter the effects of other medicines.

**Using other medicines with ETOPOSIDE-HEXAL:**

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

Certain medicines may interact with ETOPOSIDE-HEXAL. In these cases it may be necessary to change the dose or interrupt the treatment with one of the medicines.

- Ciclosporin (used after transplantation) and cisplatin (anti-cancer medicines) may increase the effect of ETOPOSIDE-HEXAL as the excretion from the body is slower.
- Co-administration of medicine like phenytoin can reduce efficacy of ETOPOSIDE-HEXAL.
- The blood clotting effect of warfarin may be reduced.
- You should not be vaccinated with live vaccines (e.g yellow fever) during treatment.
- Concurrent use of other myelosuppressive (inhibiting bone marrow activity) medicines may increase the effect.
- Sodium salicylate and aspirin (pain killers) may increase the effect of ETOPOSIDE-HEXAL.
- The effect of anthracyclines may be reduced due to cross resistance between anthracyclines and ETOPOSIDE-HEXAL.

#### **4. HOW TO USE ETOPOSIDE-HEXAL**

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

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

ETOPOSIDE-HEXAL is prescribed for adults only as safety in children has not been established.

The dose will be individually calculated and prepared for you, depending on your type\_of cancer and general condition.

This medicine is for intravenous use.

The duration of the treatment and the number of treatments is determined by the doctor and may vary for each patient.

**If you received more ETOPOSIDE-HEXAL than you should:**

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

**If you forget to use ETOPOSIDE-HEXAL:**

If you have missed a dose of your treatment, consult your doctor or a nurse.

**5. POSSIBLE SIDE EFFECTS**

ETOPOSIDE-HEXAL can have side effects.

Not all side effects reported for ETOPOSIDE-HEXAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ETOPOSIDE-HEXAL, please consult your doctor, pharmacist or other healthcare professional for advice.

If you experience the following, please consult your doctor immediately, as you may have had a negative reaction to ETOPOSIDE-HEXAL:

- Severe allergic reactions (chills, fever, swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, severe skin rashes).

The following other side-effects may occur:

*Frequent side effects:*

- Acute leukaemia (severe blood cancer)
- Myelosuppression (decreased production of blood cells and platelets)
- Leucopenia or neutropenia (decrease in number of white blood cells)
- Thrombocytopenia (decreased in blood platelets)
- Anaemia (reduction of haemoglobin causing tiredness, pale skin)
- Dizziness
- Heart attack (Myocardial infarction)
- Irregular heartbeat

- Low blood pressure causing dizziness when ETOPOSIDE-HEXAL is administered too quickly
- Abnormally high blood pressure
- Stomach pain
- Constipation
- Feeling sick (nausea)
- Being sick (vomiting)
- Loss of appetite
- Inflammation of the mucous membrane of the mouth and gullet
- Liver damage (Your doctor will monitor your liver function with blood tests during your treatment)
- Reversible loss of hair
- Darkening of skin (pigmentation)
- Rash, hives, itching
- A feeling of weakness or general discomfort
- Leakage of the medicine into the surrounding tissues (extravasation) with symptoms such as pain, irritation and swelling
- Inflammation of a vein (phlebitis)

*Less-frequent side effects:*

- Peripheral neuropathy (numbness or weakness of limbs)
- Seizures
- Inflammation of optic nerve
- Transitory loss of vision
- Tiredness and drowsiness
- Pulmonary fibrosis (scarring throughout the lungs)
- Interstitial pneumonitis (lung inflammation)
- Difficulty in swallowing
- Taste impairment

- A potentially life-threatening skin disorder accompanied by severe skin blisters and often sores in the membranes of the mouth, nose, eyes and the anal and genital areas (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- A sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (radiation recall dermatitis)

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

## 6. STORING AND DISPOSING OF ETOPOSIDE-HEXAL

- Store all medicines out of reach of children.
- Store at or below room temperature (25 °C). Protect from light.
- ETOPOSIDE-HEXAL when diluted as recommended to a concentration of 0,2 to 0,4 mg/ml in a glass container, is stable for 24 hours at room temperature and exposed to ambient daylight.
- Please return expired medicine or partially used vials to your pharmacist for safe disposal.

## 7. PRESENTATION OF ETOPOSIDE-HEXAL

**ETOPOSIDE-HEXAL 50 mg/2,5 ml:** Single 5 ml amber glass vials, closed with a fluoropolymer – coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap, packed into a single carton.

**ETOPOSIDE-HEXAL 100 mg/5 ml:** Single 5 ml amber glass vials, closed with fluoropolymer – coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap, packed into a single carton.

**ETOPOSIDE-HEXAL 200 mg/10 ml:** Single 10 ml amber glass vials, closed with fluoropolymer – coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap, packed into a single carton.

**ETOPOSIDE-HEXAL 400 mg/20 ml:** Single 20 ml amber glass vials, closed with fluoropolymer – coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap, packed into a single carton.

**ETOPOSIDE-HEXAL 1000 mg/50 ml:** Single 50 ml amber glass vials, closed with fluoropolymer – coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap, packed into a single carton.

#### **8. IDENTIFICATION OF ETOPOSIDE-HEXAL**

**ETOPOSIDE-HEXAL 50 mg/2,5 ml:** Clear, light yellow solution, free of particles

**ETOPOSIDE-HEXAL 100 mg/5 ml:** Clear, light yellow solution, free of particles

**ETOPOSIDE-HEXAL 200 mg/10 ml:** Clear, light yellow solution, free of particles

**ETOPOSIDE-HEXAL 400 mg/20 ml:** Clear, light yellow solution, free of particles

**ETOPOSIDE-HEXAL 1000 mg/50 ml:** Clear, light yellow solution, free of particles

#### **9. REGISTRATION NUMBER**

**ETOPOSIDE-HEXAL 50 mg/2,5 ml:** 37/26/0169

**ETOPOSIDE-HEXAL 100 mg/5 ml:** 37/34/0170

**ETOPOSIDE-HEXAL 200 mg/10 ml:** 37/34/0171

**ETOPOSIDE-HEXAL 400 mg/20 ml:** 37/34/0172

**ETOPOSIDE-HEXAL 1000 mg/50 ml:** 37/34/0173

#### **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Sandoz SA (Pty) Limited<sup>1</sup>

72 Steel Road

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Kempton Park

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#### **11. DATE OF PUBLICATION**

29 June 2018

<sup>1</sup> Company registration number: 1990/001979/07