Patient Information Leaflet

SCHEDULING STATUS:

S4

TERISOM (intravenous infusion 50 mg / vial)

Amphotericin B

Contains sugar (lactose monohydrate)

TERISOM contains 900 mg sucrose per via

Read all of this leaflet carefully before you are given TERISOM

- 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.

What is in this leaflet

1. What TERISOM is and what it is used for.

TERISOM contains an antifungal antibiotic amphotericin B, which is a medicine used to treat the following serious infections caused by fungi.

- Fungal infections of one or more deep organs of the body.
- Suspected fungal infections in patients with a raised temperature and neutropenia. Neutropenia is a reduced number of white blood cells called

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neutrophils. These are important in fighting infections. Neutropenia can be a side effect of cancer treatments.

- Visceral leishmaniasis, a disease caused by a parasite

2. What you need to know before TERISOM is given to you

TERISOM should not be administered to you:

- If you are hypersensitive (allergic) to the active ingredient amphotericin B or any of the other ingredients of this product. Allergic reaction symptoms including flushing, itching, sickness, swelling of the face, mouth, tongue, and airways, often enough to cause difficulty breathing.
- If you are pregnant or breastfeeding as safety in pregnancy and lactation has not been established.

Warnings and precautions

Talk to your doctor or healthcare provider before being given TERISOM:

Special care should be taken with TERISOM:

- If you have a severe allergic (anaphylaxis and anaphylactoid) reaction. If this happens your doctor will stop the infusion.
- If you experience other reactions that are thought to be related to the infusion. If this happens, your doctor might slow down the infusion, so you will receive **TERISOM** over a longer period of time (approximately 2 hours). Your doctor may also give you medicines to prevent or treat infusion-related reactions, such as diphenhydramine (an antihistamine), paracetamol, pethidine (for pain relief), and/or hydrocortisone (an anti-inflammatory medicine that works by reducing the response of your immune system).

- If you are taking other medicines that may cause kidney damage. **TERISOM** may cause damage to the kidneys. Your doctor will take regular samples to test creatinine (a chemical in the blood that reflects kidney function) and electrolyte levels (particularly potassium and magnesium) which can be abnormal due to reduced kidney function. The blood samples will also be tested for changes in your liver, and your body's ability to produce new blood cells and platelets.
- If you are receiving or have just received a leukocyte (white blood cell) transfusion. Sudden and severe problems in the lungs can happen if you are given **TERISOM** infusion during or shortly after a white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems, and your lungs will be monitored.
- If you are diabetic because **TERISOM** contains approximately 900 mg of sucrose in each vial.
- If the results of your blood tests show a change in kidney function or other important changes.

Children and adolescents

TERISOM has been used to treat children aged from 1 month to 18 years old. **TERISOM** has not been studied in babies under one month old.

Other medicines and TERISOM:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines). If they are taken with **TERISOM** their effect or the effect of **TERISOM** may cause undesirable interactions. In particular, tell your doctor or pharmacist if you are taking any of the following medicines.

Medicines that may cause kidney damage, including:

- Medicines that suppress the immune system (immunosuppressants) such as cyclosporine
- Any of the group of antibiotics known as aminoglycosides, including gentamycin, neomycin and streptomycin.
- Pentamidine (antimicrobial medication).

Medicines that may lower your potassium levels:

- Corticosteroids (anti-inflammation medicines that work by reducing the response of your immune system) and corticotrophin, used to control the amount of corticosteroid produced by your body.
- Diuretics, medicines that increase the amount of urine your body produces, for example furosemide.
- Digitalis glycosides used to treat heart failure. **TERISOM** may worsen the side effects of digitalis, such as heart rhythm changes.
- Skeletal muscle relaxants, usually used during surgery, such as tubocurarine. **TERISOM** may increase the muscle relaxant effect.

Other medicines:

- Antifungals such as flucytosine. **TERISOM** may worsen the side effects of flucytosine
- Anticancer medicines such as methotrexate, doxorubicin, carmustine and cyclophosphamide. Taking this type of medicine with **TERISOM** may cause kidney damage, wheezing or trouble breathing and low blood pressure.
- White blood cell (Leukocyte transfusions). Sudden and severe problems in the lungs can happen if you are given **TERISOM** infusion during or shortly after a

white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems and your lungs will be monitored

TERISOM *with food drink and alcohol:*

No interaction has been reported with food, drink and alcohol.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this medicine.

The safety of **TERISOM** during pregnancy is not known

Breast-feeding

If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with **TERISOM.**

Driving and using machinery:

Do not drive or operate machinery.

Some of the possible side effects of **TERISOM** could affect your ability to drive or use machines safely, See Section 4, Possible side effects.

TERISOM contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before **TERISOM** is administered.

3. How to use TERISOM:

TERISOM is always given to you by a doctor or nurse. The dosage of **TERISOM** is dependent on body weight and is adjusted to meet the needs of each individual patient. Your doctor will decide on the appropriate dosage for you.

Suspected fungal infections:

The recommended daily dose is 3 mg per kg of body weight, per day.

Fungal infections of one or more deep organs of the body:

The recommended daily dose is 3-5 mg per kg of body weight, per day. The duration of therapy will be determined on an individual basis by your Doctor.

Fungal infection of the tissues covering the brain and spinal cord (Cryptococcal meningitis)

The recommended daily dose is 6 mg per day.

Visceral leishmaniasis:

The recommended daily dose is 3 - 4 mg/day.

Your doctor will decide on the amount of **TERISOM** you will receive and over how many days it will be given.

Children

TERISOM has been used to treat children aged from 1 month to 18 years old.

TERISOM has not been studied in babies under 1 month old.

Elderly

No change in dose or frequency of infusion is required for elderly patients.

Patients with reduced kidney function:

No change in dose or frequency of infusion is required. Your doctor will take regular blood samples to test for changes in kidney function.

If you have the impression that the effect of **TERISOM** is too strong or too weak, talk to your doctor or pharmacist. The dose will be controlled in regular intervals by your doctor and adapted if necessary.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Method of administration:

To prepare the infusion **TERISOM** must be dissolved in sterile water for injection and then diluted with a solution containing dextrose.

TERISOM must not be mixed with saline (salt) solutions or with other medicinal products or electrolytes.

If you receive a higher dose of **TERISOM** than you should:

Since a health care provider will administer **TERISOM** he / she will control the dosage. However in the event of over dosage, your doctor will manage the overdosage.

If you forget to use **TERISOM**:

Since a health care provider will administer **TERISOM** it is unlikely that the dose will be missed.

If you have any further questions on the use of this medicine, ask your doctor pharmacist or nurse.

4. Possible side effects

TERISOM can have side effects.

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

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

- A severe, potentially life-threatening allergic reaction (anaphylactic reactions)
- A pink or red rash with or without pus-filled bumps or blisters, scaly, flaky skin, fever, facial swelling, swollen or tender lymph nodes, swollen saliva glands, dry mouth (Hypersensitivity reaction)

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

Tell your doctor immediately if you notice any of the following:

- Difficulty in breathing, wheezing or coughing (bronchospasm)
- A condition in which there is a decreased number of red blood cells (anaemia)
- Heart attack (cardiac arrest)
- Painless swelling under the skin (angioneurotic oedema)

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:

- Low potassium levels in the blood (Hypokalaemia)
- Low magnesium levels in the blood (Hypomagnesaemia)
- Low calcium levels in the blood (hypocalcaemia)
- High sugar (glucose) levels in the blood (hyperglycaemia)

- low sodium levels in the blood (hyponatraemia)
- Headache
- Fast heart beat (Tachycardia)
- Widening of blood vessels (Vasodilation)
- Flushing
- Low blood pressure (Hypotension)
- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Your liver is inflamed (Liver function test abnormal)
- Abnormally high levels of bilirubin (hyperbilirubinaemia)
- Increased liver enzyme (Alkaline phosphatase increased).
- Increased creatinine
- Blood urea increased
- Rash
- Back pain
- Fever or high temperature (pyrexia)
- A sudden feeling of cold with shivering accompanied by a rise in temperature (rigors)
- Chest pain

Less frequent side effects:

- Low blood platelet count (Thrombocytopenia)
- Convulsion

- Changes in the way the heart beats (arrhythmia)
- Kidney disease where you pass little or no urine (renal failure)
- Poor function of the kidneys (renal insufficiency)
- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolosis)
- Joint pain (arthralgia)

Side effects during the infusion

Frequent side effects: fever, chills, and shivering.

Less frequent infusion-related side effects include: chest tightness, chest pain, breathlessness, difficulty breathing (possibly with wheezing), flushing, a faster heart rate than normal, low blood pressure and musculoskeletal pain (described as joint pain, back pain, or bone pain).

These side effects clear up quickly when the infusion is stopped. These reactions may not happen with future infusions of **TERISOM** or with a slower infusion (over 2 hours). Your doctor may give you other medicines to prevent infusion-related reactions, or to treat the symptoms if you do get them. If you have a severe infusion-related reaction, your doctor will stop the **TERISOM** infusion and you should not receive this treatment in the future. 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 **TERISOM**.

5. How to store TERISOM

TERISOM unopened vials:

Store all medicines out of reach of children.

Store at or below 25 °C.

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

6. Contents of the pack and other information

What TERISOM contains

Distearoylphosphatidyl glycerol, Hydrogenated soya phosphatidylcholine, Cholesterol NF, Alpha-Tocopherol USP, Sucrose NF, Sodium succinate dibasic hexahydrate.

What TERISOM looks like and contents of the pack

Yellow lyophilised cake or powder, free of visible evidence of contamination.

Reconstituted solution: Yellow coloured suspension free from visible foreign particulate matter.

TERISOM is presented in 15 ml, 20 ml or 30 ml sterile, Type I glass vials. The closure consists of a grey butyl rubberstopper and aluminium ring seal fitted with a removable plastic cap. Single-dose vials are packed ten per carton with 10 filters. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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