PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LEVUSPOZ 50 AND LEVUSPOZ 100

(powder for solution for infusion)

Micafungin Sodium

Contains sugar: Lactose monohydrate 223,15 mg per vial

Read all of this leaflet carefully before you are given LEVUSPOZ

- 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 LEVUSPOZ is and what it is used for

LEVUSPOZ contains the active substance micafungin and is available as powder for concentrate for solution for infusion.

LEVUSPOZ is called an antifungal medicine because it is used to treat infections caused by fungal cells.

LEVUSPOZ is used to treat fungal infections caused by fungal or yeast cells called *Candida.*

LEVUSPOZ is effective in treating systemic infections (those that have penetrated within the body). It interferes with the production of a part of the fungal cell wall. An intact cell wall is necessary for the fungus to continue living and growing. LEVUSPOZ causes defects in the fungal cell wall, making the fungus unable to live and grow.

Your doctor has prescribed LEVUSPOZ for you in the following circumstances when there are no other suitable antifungal treatments available (see section 2):

- To treat adults, adolescents and children including neonates who have a serious fungal infection called invasive candidiasis (infection that has penetrated the body).
- To treat adults and adolescents ≥ 16 years of age who have a fungal infection in the gullet (oesophagus) where treatment through injection (intravenous) is appropriate.
- To prevent infection with a bacteria called *Candida* if you are having a bone-marrow transplant or are expected to have a neutropenia (low levels of neutrophils, a type of white blood cell) for 10 days or more.

2. What you need to know before you take LEVUSPOZ

LEVUSPOZ should not be administered to you

- if you are allergic (hypersensitive) to micafungin, other echinocandins or to any of the ingredients in LEVUSPOZ.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

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

- if you have severe liver problems (e.g. liver failure or hepatitis) or have had abnormal liver function tests. During treatment your liver functions will be monitored more closely.
- if you develop severe allergic reaction towards LEVUSPOZ. Symptoms may include rash and rigors (a sudden feeling of cold with shivering accompanied by a rise in temperature).Also inform your doctor if you have underlying conditions such as Advanced AIDS or malignant tumour/ cancer.
- if you develop rash as it may indicate skin problems
- if you have haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells). This may be indicated by feeling tired, weakness, irregular heartbeats or shortness of breath.
- if you have kidney problems (e.g. kidney failure and abnormal kidney function test). If this happens, your doctor may decide to monitor your kidney function more closely.

Children and adolescents (below 18 years):

Children may experience more severe side effects than adults. See section 4**.**

Other medicines and LEVUSPOZ

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

It is especially important to inform your doctor if you are using amphotericin B desoxycholate or itraconazole (antifungal antibiotics), sirolimus (medicine used to suppress the immune system) or nifedipine (medicine used to treat high blood pressure) as LEVUSPOZ may increase the blood levels of these medicines in your blood. Your doctor may decide to adjust the dose of these medicines.

LEVUSPOZ with food and drink

As LEVUSPOZ is given intravenously (into a vein), no restrictions on food or drink are required.

Pregnancy, breastfeeding and fertility

You should not receive LEVUSPOZ when you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Driving and using machines

LEVUSPOZ may cause dizziness and affect the ability to concentrate. Please inform your doctor if you experience any effects that may cause you to have problems with driving or using other machinery.

It is not always possible to predict to what extent LEVUSPOZ may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LEVUSPOZ affects them.

LEVUSPOZ contains Lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before receiving LEVUSPOZ.

3. How to take LEVUSPOZ

You will not be expected to give yourself LEVUSPOZ.
It will be given to you by a person who is qualified to do so.
LEVUSPOZ should be administered once daily by slow intravenous (into a vein) infusion.
Your doctor will determine how much LEVUSPOZ you will receive each day.

Use in adults, adolescents ≥ 16 years of age and elderly

- The usual dose to treat an invasive *Candida* infection is 100 mg per day for patients weighing 40 kg or more and 2 mg/kg per day for patients weighing 40 kg or less.
- The dose to treat a *Candida* infection of the oesophagus is 150 mg for patients weighing more than 40 kg and 3 mg/kg per day for patients weighing 40 kg or less.
- The usual dose to prevent invasive *Candida* infections is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

Use in children > 4 months of age and adolescents < 16 years of age

- The usual dose to treat an invasive *Candida* infection is 100 mg per day for patients weighing 40 kg or more and 2 mg/kg per day for patients weighing 40 kg or less.
- The usual dose to prevent invasive *Candida* infections is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

Use in children and newborns < 4 months of age

- The usual dose to treat an invasive *Candida* infection is 4-10 mg/kg per day.
- The usual dose to prevent invasive *Candida* infections is 2 mg/kg per day

If you receive more LEVUSPOZ than you should

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

If you forget to take LEVUSPOZ

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

If you stop taking LEVUSPOZ

There are no known withdrawal symptoms.

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

4. Possible side effects

LEVUSPOZ can have side effects.

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

If any of the following happen, stop receiving LEVUSPOZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- severe skin reaction (e.g. blistering and peeling of the skin) rash
- fainting and shock
- severe condition of the skin that may affect the mouth and other parts of the body (erythema multiforme)
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens- Johnson syndrome)
- sudden life-threatening allergic reaction (Anaphylactoid shock)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LEVUSPOZ. 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:

- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of frequent infections such as fever or sore throat
- less urine than is normal for you
- yellowing of the skin and eyes, also called jaundice
- liver damage/disease (hepatocellular damage including fatal cases)

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

Frequent side effects:

Tell your doctor if you notice any of the following:

- nausea (feeling sick), vomiting
- stomach pains
- headache
- diarrhoea
- Fever
- shivering
- decreased white blood cell (Leukopenia/ Neutropenia)
- decreased number of red blood cells (Anaemia)

- low potassium levels in the blood (Hypokalaemia)
- low magnesium levels in the blood (Hypomagnesaemia)
- low calcium levels in the blood (Hypocalcaemia)
- increased blood alkaline phosphatase, which may have symtops such as dark-colored urine and/or light-colored stool, swelling and pain in your stomach, itching or nausea and vomiting
- increased aspartate aminotransferase or increased alanine aminotransferase which may have symptoms such as swelling in your ankles and legs, tiredness, nausea and vomiting, weight loss or dark-colored urine
- increased blood bilirubin (including hyperbilirubinaemia), which may have symptoms such as abdominal pain or swelling, chills, fever, chest pain, weakness, lightheadedness, fatigue and nausea.
- abnormal liver function test

Less frequent side effects:

- dizziness
- loss of appetite
- inflammation at the injection site
- increased sweating
- difficulty in sleeping
- anxiety
- disturbed taste
- increase or decrease in blood pressure (Hypotension or Hypertension)
- low blood platelet count (Thrombocytopenia)

- a decrease in albumin in the blood, causing water retention (Hypoalbuminaemia)
- low sodium levels in the blood (Hyponatraemia)
- high potassium levels in the blood (Hyperkalaemia)
- low phosphate levels in the blood (Hypophosphataemia)
- reddening of your skin called flushing
- increased blood lactate dehydrogenase, which usually means you have some type of tissue damage or disease

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 LEVUSPOZ.

5. How to store LEVUSPOZ

Store at or below 30 °C.

Protect from light.

Store in original package.

Store all medicines out of reach of children.

Do not use LEVUSPOZ after the expiry date which is stated on the vial and on the carton. The expiry date refers to the last day of that month.

The unopened vial does not require any special storage conditions.

The reconstituted concentrate and the diluted infusion solution should be used immediately.

Do not use the diluted infusion solution if it is cloudy or precipitated.

In order to protect the infusion bottle / bag containing the diluted infusion solution from light it should be inserted into a closable opaque bag.

The vial is for single use only. Therefore, please discard unused reconstituted concentrate immediately.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Reconstituted LEVUSPOZ should be used immediately because it does not contain any preservatives to prevent bacterial contamination. Only a trained health care professional who has read the complete directions properly can prepare LEVUSPOZ for use.

6. Contents of the pack and other information

What LEVUSPOZ contains

The active substance is Micafungin.

The other ingredients are lactose monohydrate (low endotoxin), citric acid, sodium hydroxide (as solution 0,1 %), water for Injection and nitrogen.

What LEVUSPOZ looks like and contents of the pack

LEVUSPOZ 50 and 100:

5 clear, amber glass vials with a rubber stopper and aluminium closure with red or blue plastic disc, containing solid white to off white powder, packed in a carton box together with the leaflet.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICAL (PTY) LTD

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This leaflet was last revised in

Date of registration: 25 July 2023

Application number

LEVUSPOZ 50 : 57/20.2.2/0119

LEVUSPOZ 100: 57/20.2.2/0120

Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/