PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Micafungin 50 Sandoz (powder for concentrate for solution for infusion)

Micafungin 100 Sandoz (powder for concentrate for solution for infusion)

Active ingredient: Micafungin sodium.

MICAFUNGIN SANDOZ contains sugar (lactose) 200 mg per vial.

Read all of this leaflet carefully before you are given MICAFUNGIN SANDOZ

- 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 MICAFUNGIN SANDOZ is and what it is used for

MICAFUNGIN SANDOZ contains the active substance micafungin. MICAFUNGIN SANDOZ is called an antifungal medicine because it is used to treat infections caused by fungal or yeast cells called Candida.

Your doctor has prescribed MICAFUNGIN SANDOZ 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 into a vein (intravenous) is appropriate.
- To prevent infection with Candida in patients who are having a bone-marrow transplant or who are expected to have neutropenia (low levels of neutrophils, a type of white blood cell) for 10 days or more.

How it works:

MICAFUNGIN SANDOZ 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. MICAFUNGIN SANDOZ causes defects in the fungal cell wall, making the fungus unable to live and grow.

2. What you need to know before you are given MICAFUNGIN SANDOZ

MICAFUNGIN SANDOZ should not be administered to you if:

you are hypersensitive (allergic) to micafungin, other echinocandins (e.g. caspofungin or anidulafungin) or any of the other ingredients of MICAFUNGIN SANDOZ (listed in section 6).

Warnings and precautions:

In rats, long-term treatment with micafungin led to liver damage and subsequent liver tumours. The potential risk of developing liver tumours in humans is not known, and your doctor will assess the benefits and risks of MICAFUNGIN SANDOZ treatment before starting your medicine. Please tell your doctor 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.

Tell your doctor or pharmacist before being given the injection:

- If you have had allergies to any medicines.
- If you have haemolytic anaemia / haemolysis (anaemia due to breakdown of red blood cells). Your doctor will monitor you to see whether there is any evidence that the condition may have developed or become worse, and then decide whether to continue treatment.
- If you have had kidney problems (e.g. kidney failure and abnormal kidney function test) or liver problems (e.g. liver failure, hepatitis or have had abnormal liver function tests). Your doctor may decide to monitor your kidney or liver function more closely.
- If you develop a rash or severe inflammation or eruption of the skin and mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis). If this happens you doctor will monitor this closely and may decide to stop therapy.
- The occurrence of some of the above warnings and precautions was greater in children than adult patients.

Other medicines and MICAFUNGIN SANDOZ:

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

It is especially important to inform your doctor if you are using amphotericin B desoxycholate or itraconazole (antifungal antibiotics), sirolimus (an immunosuppressant) or nifedipine (calcium

channel blocker used to treat high blood pressure). The administration of MICAFUNGIN SANDOZ together with these medicines may cause them to be more toxic. Your doctor may decide to reduce the dose of these medicines.

Pregnancy and breastfeeding:

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 health care provider for advice before taking this medicine.

Driving and using machines:

Micafungin is unlikely to have an effect on driving or using machines. However some people may feel dizzy when taking this medicine and if this happens to you, do not drive or use any tools or machines. Please inform your doctor if you experience any effects that may cause you to have problems with driving or using other machinery.

Important information about some of the ingredients of MICAFUNGIN SANDOZ:

MICAFUNGIN SANDOZ contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MICAFUNGIN SANDOZ.

3. How to use MICAFUNGIN SANDOZ

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

MICAFUNGIN SANDOZ should be given to you over approximately 1 hour by slow infusion (a drip) into your vein. Your doctor will determine how much MICAFUNGIN SANDOZ you will receive based on your weight.

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.
- 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.
- To prevent infection with Candida in patients who are having a bone-marrow transplant or who are expected to have neutropenia (low levels of neutrophils, a type of white blood cell), 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.

Your doctor will tell you how long your treatment with MICAFUNGIN SANDOZ will last. If you have the impression that the effect of MICAFUNGIN SANDOZ is too strong or too weak, tell your doctor or pharmacist.

If you receive more MICAFUNGIN SANDOZ than you should:

Since a health care provider will administer MICAFUNGIN SANDOZ, they will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

If you are concerned that you may have been given too much MICAFUNGIN SANDOZ, tell your doctor or other health care provider immediately.

If you forget to use MICAFUNGIN SANDOZ:

Since a health care provider will administer MICAFUNGIN SANDOZ, it is unlikely that the dose will be missed. Tell your doctor, pharmacist or other health care provider if you think that a dose has been forgotten.

If you stop using MICAFUNGIN SANDOZ:

You should not experience any effects from MICAFUNGIN SANDOZ if your doctor stops treatment.

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

4. Possible side effects

MICAFUNGIN SANDOZ can cause side effects.

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

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

- An allergic attack
    - Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
    - Sudden contraction of the muscles around the airways resulting in difficulty in breathing, wheezing or coughing.
    - Skin flushing (erythema).
    - Hot flush.
    - Itchy rash (urticaria), pruritus (itching), hives.
- A severe skin reaction (e.g. blistering and peeling of the skin).

These are very serious side effects. If you have them you may have had a serious reaction to MICAFUNGIN SANDOZ. 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:

- A decrease in white blood cells (leucopenia; neutropenia).

- A decrease in red blood cells (anaemia, haemolytic anaemia, haemolysis).
- A decrease in blood cells (pancytopenia).
- A decreased in blood platelets (thrombocytopenia).
- An increase in a certain type of white blood cell called eosinophils.
- A decrease in albumin in the blood (hypoalbuminaemia).
- Disorder of blood clotting system.
- Low blood potassium (hypokalaemia).
- Low blood magnesium (hypomagnesaemia).
- Low blood calcium (hypocalcaemia).
- Low blood sodium (hyponatraemia).
- High blood potassium (hyperkalaemia).
- Low blood phosphate (hypophosphataemia).
- Liver Disorders
    - Abnormal liver function tests (increased alkaline phosphatase; increased aspartate aminotransferase, increased alanine aminotransferase).
    - Increased bile pigment in the blood (hyperbilirubinaemia).
    - Liver failure; increased liver enzymes (gamma-glutamyltransferase).
    - Jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems).
    - Reduced bile reaching the intestine (cholestasis); enlarged liver; liver inflammation.
    - Damage to liver cells including death.
- Kidney Disorders
    - Abnormal kidney function tests (increased blood creatinine; increased urea in the blood).
    - Aggravated / acute kidney failure.
- Collection of fluid in your body.
- increased or decreased heart rate; irregular heartbeat.
- high or low blood pressure.

- increase in an enzyme called lactate dehydrogenase.

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:

- Headache.
- Nausea (feeling sick).
- Vomiting (being sick).
- Diarrhoea.
- Abdominal pain.
- Anorexia (eating disorder).
- Fever.
- Rigors (shivering).
- Inflammation / pain at injection site.

Less frequent side effects:

- Increased sweating.
- Indigestion.
- Constipation.
- Clotting in the vein at the injection-site.
- Insomnia (difficulty in sleeping).
- Anxiety.
- Confusion.
- Feeling lethargic (somnolence); trembling; dizziness.
- Disturbed taste.

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 or pharmacist.

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 MICAFUNGIN SANDOZ.

Suspected adverse reactions can also be reported directly to the company via Patientsafety.sacg@novartis.com.

5. How to store MICAFUNGIN SANDOZ

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- **Unopened vial:**

  Store in the original package in order to protect from light. Product can withstand direct light exposure for up to 60 days (2 months).
- **Reconstituted concentrate in vial:**

  The reconstituted solution may be stored at up to 25 °C for up to 24 hours.
- **Infusion solution:**

  The infusion solution may be stored at 25 °C for 24 hours. Do not freeze.
- Do not use MICAFUNGIN SANDOZ if you notice that the solution is not clear, or you see particles in the solution.
- The reconstituted concentrate and the diluted infusion solution should be used immediately, because it does not contain any preservatives to prevent bacterial contamination.
- The vial is for single use only.

This product should not be used after the expiry date printed on the label / carton.

6. Contents of the pack and other information

What MICAFUNGIN SANDOZ contains:

- The active substance is micafungin sodium. 1 vial contains micafungin sodium equivalent to 50 mg or 100 mg micafungin.
- The other ingredients are lactose monohydrate, citric acid (for pH-adjustment) and sodium hydroxide (for pH adjustment).

What MICAFUNGIN SANDOZ looks like and contents of the pack:

MICAFUNGIN SANDOZ 50mg or 100 mg powder for concentrate for solution for infusion is a white to off-white freeze-dried powder.

MICAFUNGIN 50 SANDOZ, Powder for concentrate for solution for infusion is packed in a 10 ml glass vial wrapped with transparent UV-resistant protection film, closed with a rubber stopper and sealed with an aluminium seal and blue plastic flip-off cap.

MICAFUNGIN 100 SANDOZ, Powder for concentrate for solution for infusion is packed in a 10 ml glass vial wrapped with transparent UV-resistant protection film, closed with a rubber stopper and sealed with an aluminium seal and red plastic flip-off cap.

MICAFUNGIN SANDOZ is supplied in a box containing 1 vial.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

13 June 2023

Registration numbers

MICAFUNGIN 50 SANDOZ: 55/20.2.2/0495

MICAFUNGIN 100 SANDOZ: 55/20.2.2/0496

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07