PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Mycamine 50 mg powder for solution for infusion (50 mg micafungin)

Mycamine 100 mg powder for solution for infusion (100 mg micafungin)

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

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

Mycamine 50 mg: Each vial contains 50 mg of micafungin (as sodium salt).

Mycamine 100 mg: Each vial contains 100 mg of micafungin (as sodium salt).

Mycamine 50 mg contains sugar (200 mg lactose monohydrate per vial).

Mycamine 100 mg contains sugar (200 mg lactose monohydrate per vial).

The other ingredients are citric acid anhydrous and sodium hydroxide.

WHAT MYCAMINE IS USED FOR:

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

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

BEFORE YOU RECEIVE MYCAMINE:

Do not receive Mycamine:

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

Take special care with Mycamine:

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.
- if you have haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells).
- 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.

Receiving Mycamine with food and drink:

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

Pregnancy and Breastfeeding:

You should not receive Mycamine when you are pregnant or breastfeeding your baby.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Driving and using machinery:

There is no information on the effect of Mycamine on the ability to drive or use 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 Mycamine:

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

Taking other medicines with Mycamine:

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). Your doctor may decide to adjust the dose of these medicines.

HOW MYCAMINE IS ADMINISTERED:

Mycamine must be prepared and given to you by a doctor or another healthcare professional.

Mycamine should be administered once daily by slow intravenous (into a vein) infusion. Your doctor will determine how much Mycamine you will receive each day.

If you receive more Mycamine than you should:

Your doctor monitors your response and condition to determine what dose of Mycamine is needed.

However, if you are concerned that you may have been given too much Mycamine, speak to your doctor or another healthcare professional immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you miss a dose of Mycamine:

Your doctor monitors your response and condition to determine what Mycamine treatment is needed.

However, if you are concerned that you may have missed a dose, speak to your doctor or another health care professional immediately.

Effects when treatment with Mycamine is stopped:

There are no known withdrawal symptoms.

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

POSSIBLE SIDE EFFECTS:

Mycamine can cause side effects.

Not all side effects reported for Mycamine are included in this leaflet. Should your general health worsen while receiving Mycamine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop receiving Mycamine 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
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Mycamine. You may need urgent medical attention or hospitalisation. All of these serious side effects are less frequent.

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

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
- dizziness
- weakness, tiredness, poor concentration
- light-headedness
- diarrhoea
- loss of appetite
- shivering
- inflammation at the injection site
- increased sweating
- difficulty in sleeping
- anxiety, disturbed taste

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

STORING AND DISPOSING OF MYCAMINE:

Store at or below 25°C.

Protect from light.

Store in original package.

Store all medicines out of reach of children.

Do not use Mycamine 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 Mycamine 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 Mycamine for use.

PRESENTATION OF MYCAMINE:

Mycamine 50 mg: 10 ml Type I glass vial with an isobutylene-isoprene (Fluoro resin film laminated) grey rubber stopper and a blue flip-off cap. The vial is wrapped with a UV-protective film. Supplied in packs of 1 vial.

Mycamine 100 mg: 10 ml Type I glass vial with an isobutylene-isoprene (Fluoro resin film laminated) grey rubber stopper and a red flip-off cap. The vial is wrapped with a UV-protective film. Supplied in packs of 1 vial.

IDENTIFICATION OF MYCAMINE:

White mass powder for solution for infusion.

REGISTRATION NUMBERS:

Mycamine 50 mg: 44/20.2.2/0639

Mycamine 100 mg: 44/20.2.2/0640

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Sandoz SA (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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