PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MYGIN™ 50, powder for solution for infusion

MYGIN™ 100, powder for solution for infusion

Micafungin (as sodium)

Contains sugar (lactose)

MYGIN 50: 200 mg lactose monohydrate/vial

MYGIN 100: 200 mg lactose monohydrate/vial

Read all of this leaflet carefully before you are given MYGIN

- 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 MYGIN is and what it is used for

MYGIN contains the active substance micafungin. It is called an antifungal medicine, because it is used to treat infections caused by fungal cells.

MYGIN is used:

- 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 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 are given MYGIN

MYGIN should not be administered to you:

- if you are hypersensitive (allergic) to micafungin or any of the other ingredients of MYGIN (listed in section 6).
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Special care should be taken with MYGIN:

Tell your doctor or healthcare provider before being given MYGIN 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
- are allergic to any medicine

- had previously received MYGIN and you had a skin reaction to the medicine (Stevens-Johnson syndrome or toxic epidermal necrolysis)
- have haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells)
- have kidney problems and abnormal kidney function test. If this happens, your doctor will monitor your kidney function more closely.

Children and adolescents

Children are more likely to experience side effects than adults (see section 4).

Other medicines and MYGIN

Always tell your healthcare provider if you are taking any other medicine.

This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using, or have recently taken or used:

- Antifungal antibiotics, such as amphotericin B desoxycholate or itraconazole, used to treat fungal infections.
- Sirolimus, an immunosuppressant used to treat auto-immune diseases (where the body attacks its own cells).
- Nifedipine, a medicine used to treat high blood pressure.

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

MYGIN with food and drink

Not applicable, MYGIN is given intravenously (into a vein).

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before being given MYGIN.

You must not receive MYGIN if you are pregnant or breastfeeding your baby (see "MYGIN should not be administered to you").

MYGIN may affect fertility in men.

Driving and using machines

MYGIN may cause dizziness.

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

3. How MYGIN will be administered

You will not be expected to give yourself MYGIN. It will be given to you by a doctor or other healthcare provider who is qualified to do so.

MYGIN is given to you once daily by a slow intravenous (into a vein) infusion, over approximately one hour. Your doctor/healthcare provider will ensure that you receive the correct dose.

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.

Your doctor will tell you how long your treatment with MYGIN will last.

If you have the impression that the effect of MYGIN is too strong or too weak, tell your doctor or pharmacist.

If you receive more MYGIN than you should

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

If you missed a dose of MYGIN

Since a healthcare provider will administer MYGIN, it is unlikely that the dose will be missed.

4. Possible side effects

MYGIN can have side effects.

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

If any of the following happens, stop receiving MYGIN and tell your doctor immediately:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Welts, urticaria (hives), red skin, widespread severe rash or itching.
- Fainting or shock.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYGIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately 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 or recurrent infections such as fever or sore throat – you may have a low white blood cell count
- If you experience a rare, serious disorder of your skin and mucous membranes. It begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters (Stevens-Johnson syndrome)
- If you experience a potentially life-threatening dermatologic disorder characterised by widespread blistering and peeling of the skin (toxic epidermal necrolysis)
- Less urine than is normal for you
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

- Decreased number of blood cells which can make the skin pale (anaemia) and cause weakness or breathlessness
- Low levels of potassium, magnesium and calcium in the blood (determined by a blood test)

- Headache
- Inflammation of a vein (redness, swelling, warm, tenderness)
- Nausea (feeling sick), vomiting (being sick), diarrhoea (watery stools), stomach pain
- Abnormal liver function tests (increased alkaline phosphatase, increased aspartate aminotransferase, increased alanine aminotransferase)
- Increased bile pigment in the blood (hyperbilirubinaemia)
- Fever and chills (a sudden feeling of cold with shivering)
- Rash

Less frequent side effects

- Abnormal blood test results, decreased blood cells (pancytopenia), decreased blood platelets (thrombocytopenia), increases in a certain type of white blood cells called eosinophils, decreased albumin in the blood (hypoalbuminaemia)
- Disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia)
- Excessive sweating
- Low levels of sodium and phosphate in the blood (determined by a blood test)
- High levels of potassium in the blood (which can cause abnormal heart rhythm)
- Loss of appetite
- Anxiety, confusion
- Sleeplessness, sleepiness, feeling lethargic
- Shaking, trembling, dizziness

- Taste disorder
- Low or high blood pressure
- Flushing (skin or face becomes red and hot)
- Heartburn/indigestion, constipation (difficulty to pass stools)
- Abnormal kidney function tests (increased blood creatinine, increased urea in the blood), aggravated kidney failure
- Pain, redness and swelling at the infusion site as a result of injury or irritation causing dilatation of the blood capillaries
- Swelling of lower legs or hands
- Clotting in vein at injection-site, inflammation at injection-site, pain at injection-site, collection of fluid in your body
- Increase in an enzyme called lactate dehydrogenase.

Frequency unknown:

- Abnormal blood clotting (determined by a blood test)
- Damage to liver cells including death
- Sudden and often temporary loss of kidney function.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of MYGIN.

5. How MYGIN will be stored

Store all medicines out of reach of children.

Store unopened vial at or below 25 °C in the original carton in order to protect from light.

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

Do not use after the expiry date printed on the container/label/carton. The expiry date refers to the last day of that month.

Only a trained healthcare professional who has read the complete directions properly can prepare MYGIN for use. Do not use the diluted infusion solution if it is cloudy or precipitated. The reconstituted solution 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. Discard unused reconstituted concentrate immediately.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MYGIN contains

The active ingredient is micafungin (as sodium).

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

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

The other ingredients are anhydrous citric acid, lactose monohydrate and sodium hydroxide.

What MYGIN looks like and contents of the pack

MYGIN is a white lyophilised solid powder for solution for infusion.

MYGIN 50 & 100, once reconstituted or diluted presents as a clear, colourless liquid. The reconstituted or diluted solution is sterile, pyrogen-free and free of visible particles.

MYGIN 50 is packed in a 10 ml Type I clear glass vial sealed with a grey chlorobutyl rubber stopper, laminated with ethylene tetrafluoroethylene (ETFE-laminated) and a blue flip-off cap.

MYGIN 100 is packed in a 10 ml Type I clear glass vial sealed with a grey chlorobutyl rubber stopper, laminated with ethylene tetrafluoroethylene (ETFE-laminated) and a red flip-off cap.

Each vial is packed in a small carton.

Holder of Certificate of Registration

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