PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MICONONIN 50 mg powder for solution for infusion

MICONONIN 100 mg powder for solution for infusion

Micafungin

Contains sugar: lactose monohydrate

Read all of this leaflet carefully before you are given MICONONIN

- 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 MICONONIN is and what it is used for

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

MICONONIN is used to treat fungal infections caused by fungal or yeast cells called *Candida*. MICONONIN is effective in treating systemic infections (those that have penetrated within the body).

2. What you need to know before you MICONONIN is administered

MICONONIN should not be administered to you:

- If you are hypersensitive (allergic) to micafungin or any of the other ingredients of MICONONIN (listed in section 6).

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 inflammation of the liver) 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.
- If you are allergic to any medicine.
- If you are receiving sirolimus (an immunosuppressant).
- If you are pregnant or breastfeeding.

MICONONIN may also cause severe inflammation/eruption of the skin and mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Children

Experience with MICONONIN in children less than 2 years of age is limited.

Other medicines and MICONONIN

Always tell your health care 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 any of the following:

- amphotericin B or itraconazole (antifungal antibiotics),
- sirolimus (an immunosuppressant) or,
- nifedipine (calcium channel blocker used to treat high blood pressure).

Your doctor may decide to adjust 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.

MICONONIN should not be used if you are pregnant or breastfeeding your baby.

Driving and using machines

MICONONIN is unlikely to have an effect on driving or using machines. However, some people may feel drowsy and or dizzy when receiving MICONONIN and if this happens to you, do not drive or use any machines.

MICONONIN contains lactose monohydrate

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not receive MICONONIN.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

3. How MICONONIN is administered

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

If you receive more MICONONIN than you should

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

If you miss a dose of MICONONIN

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

4. Possible side effects

MICONONIN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

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

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

Tell your doctor if you notice any of the following:

Frequent

- abnormal blood tests (decreased white blood cells [leucopenia; neutropenia]), decreased red blood cells (anaemia),
- decreased potassium in the blood (hypokalaemia); decreased magnesium in the blood (hypomagnesaemia); decreased calcium in the blood (hypocalcaemia),
- headache,
- inflammation of the vein wall (at injection-site),
- nausea (feeling sick); vomiting (being sick); diarrhoea; abdominal pain,
- abnormal liver function tests (increased alkaline phosphatase; increased aspartate aminotransferase, increased alanine aminotransferase),
- increased bile pigment in the blood (hyperbilirubinaemia),
- rash,

- fever,
- rigors (shivering).

Less frequent

- abnormal blood tests (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),
- anaemia due to breakdown of red blood cells (haemolytic anaemia), breakdown of red blood cells (haemolysis),
- hypersensitivity,
- increased sweating,
- decreased sodium in the blood (hyponatraemia); increased potassium in the blood (hyperkalaemia); decreased phosphates in the blood (hypophosphataemia); anorexia (eating disorder),
- insomnia (difficulty in sleeping); anxiety; confusion,
- feeling lethargic (somnolence); trembling; dizziness; disturbed taste,
- increased heart rate; stronger heartbeat; irregular heartbeat,
- high or low blood pressure; skin flushing,
- shortness of breath,
- indigestion; constipation,
- 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,
- itchy rash (urticaria); itching; skin flushing (erythema),
- abnormal kidney function tests (increased blood creatinine; increased urea in the blood); aggravated kidney failure,
- increase in an enzyme called lactate dehydrogenase,

- clotting in vein at injection-site; inflammation at injection-site; pain at injection-site; collection of fluid in your body.

Frequency unknown

- disorder of blood clotting system,
- (allergic) shock,
- damage to liver cells including death,
- kidney problems; acute kidney failure.

Additional side effects in children and adolescents

Frequent

- decreased blood platelets (thrombocyropenia),
- increased heart rate (tachycardia),
- high or low blood pressure,
- increased bile pigment in the blood (hyperbilirubinaemia); enlarged liver,
- acute kidney failure; increased urea in the blood.

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 the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MICONONIN.

5. How to store MICONONIN

Store all medicines out of reach of children.

- Store at or below 25 ºC in the original package in order to protect from light. This medicine can withstand direct light exposure for up to 60 days (2 months).

Reconstituted concentrate in vial

- Store at or below 25 ºC, when reconstituted with sodium chloride 9 mg/ml (0,9 %) or dextrose 50 mg/ml (5 %) solution for infusion (Reconstituted concentrate in vial).

Diluted infusion solution

- Store at or below 25 ºC protected from light, when diluted with sodium chloride 9 mg/ml (0,9 %) or dextrose 50 mg/ml (5 %) solution for infusion (Diluted solution for infusion).

From a microbial point of view, MICONONIN 50 mg and 100 mg powder for solution for infusion contains no preservatives; the reconstituted and diluted solutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 ºC to 8 ºC, unless the reconstitution and dilution have taken place in controlled and validated aseptic conditions.

- Do not use after the expiry date stated on the label or carton.
- Do not use MICONONIN if the reconstituted solution is not clear or if you notice visible particles in the solution.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What MICONONIN contains

- The active substance is micafungin.

MICONONIN 50 mg:

Each vial contains micafungin sodium equivalent to micafungin 50 mg.

After reconstitution, each ml contains micafungin sodium equivalent to micafungin 10 mg. Contains sugar: lactose monohydrate 47,62 mg/ml.

MICONONIN 100 mg:

Each vial contains micafungin sodium equivalent to micafungin 100 mg.

After reconstitution, each ml contains micafungin sodium equivalent to micafungin 20 mg. Contains sugar: lactose monohydrate 47,62 mg/ml.

- The other ingredients are citric acid anhydrous (E330) (to adjust the pH), lactose monohydrate, sodium hydroxide (E524) (to adjust the pH) and water for injection.

What MICONONIN looks like and contents of the pack

MICONONIN is a lyophilized white to off-white powder.

MICONONIN 50: 10 ml Type I glass vial closed with an isobutylene isoprene rubber stopper and an aluminium seal with a blue plastic, flip-of cap.

MICONONIN 100: 10 ml Type I glass vial closed with an isobutylene isoprene rubber stopper and an aluminium seal with a red plastic, flip-of cap.

The vial is wrapped with a UV-protective film.

Pack size: one vial per cardboard carton.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

Address: 106 16th Road, Midrand, Gauteng, 1686.

Contact No.: +27 (0)10 045 2500

PV Email Address: pv@kahmagroup.co.za

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MICONONIN 100 mg: 56/20.2.2/0534

Access to the corresponding Professional Information

Website Address: www.kahmahealthcaregroup.co.za