PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MICAFUNGIN 50 mg ADCO (Powder for solution for infusion)

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

MICAFUNGIN 100 mg ADCO (Powder for solution for infusion)

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

Contains sugar: Lactose monohydrate 50 mg/ml

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

- 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 ADCO is and what it is used for

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

MICAFUNGIN ADCO is used to treat fungal infections caused by fungal or yeast cells called *Candida*. MICAFUNGIN ADCO 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. MICAFUNGIN ADCO causes defects in the fungal cell wall, making the fungus unable to live and grow.

MICAFUNGIN ADCO may be prescribed for you in the following circumstances when there are no other suitable antifungal treatments available:

To treat adults, adolescents ≥ 16 years and the elderly who:

- have a serious fungal infection called invasive candidiasis (infection that has penetrated the body).
- have a fungal infection in the oesophagus where treatment into a vein (intravenous) is appropriate.
- are at risk of developing a Candida fungal infection due to haematopoietic stem cell transplantation (blood cell transfer) or may have neutropenia (lack of certain white blood cells) for 10 days or more.

Children (including neonates) and adolescents < 16 years of age who:

- have a serious fungal infection called invasive candidiasis (infection that has penetrated the body)
- are at risk of developing a Candida fungal infection due to haematopoietic stem cell transplantation (blood cell transfer) or may have neutropenia (lack of certain white blood cells) for 10 days or more.

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

MICAFUNGIN ADCO should not be administered to you:

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

Warnings and precautions

The potential risk of developing liver tumours in humans is not known, and your doctor or health care provider will assess the benefits and risks of MICAFUNGIN ADCO treatment before starting your medicine. Please tell your doctor or health care provider if you have severe liver problems (e.g. liver failure or hepatitis (swelling of the liver)) or have had abnormal liver function tests. During treatment your liver functions will be monitored more closely.

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

- if you are allergic to any medicine
- 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.

Micafungin may also cause Stevens-Johnson syndrome (severe swelling of the skin as an allergic reaction to the medicine).

Children and adolescents

The incidence of some adverse reactions may be higher in paediatric patients than in adults.

Other medicines and MICAFUNGIN ADCO

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

(This includes complementary or traditional medicines.)

Tell your health care provider if you are taking any of the following medicines as the dose may need to be adjusted:

- Itraconozole or Amphoteracin B desoxycholate for the treatment of fungal infections
- Sirolimus, which lowers the body's normal immune response
- Nifedipine, blood pressure medicine

MICAFUNGIN ADCO with food and drink

As MICAFUNGIN ADCO is given into a vein, no restrictions on food or drink are required.

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 health care provider for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

MICAFUNGIN ADCO should not be used during pregnancy or breastfeeding.

MICAFUNGIN ADCO may have the potential to affect male fertility.

Driving and using machines

MICAFUNGIN ADCO may cause dizziness.

It is not always possible to predict to what extent MICAFUNGIN ADCO may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which MICAFUNGIN ADCO affects you.

3. How you will be given MICAFUNGIN ADCO

MICAFUNGIN ADCO will be administered by an Intravenous (IV) infusion into your vein. You will not be expected to give yourself MICAFUNGIN ADCO. It will be given to you by a person who is qualified to do so.

The dose regimen of MICAFUNGIN ADCO depends on your body weight and will be decided by your doctor.

Treatment for invasive Candida infection is usually a minimum of 14 days. Your doctor will tell you how long your treatment with MICAFUNGIN ADCO will last. If you have the impression that the effect of MICAFUNGIN ADCO is too strong or too weak, tell your doctor or pharmacist.

If you receive more MICAFUNGIN ADCO than you should

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

If you forget to receive MICAFUNGIN ADCO

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

4. Possible side effects

MICAFUNGIN ADCO can have side effects.

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

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

- Swelling of the hands, feet, ankles, face and neck, which may cause difficulty in swallowing or breathing. This may be the sign of an allergic reaction and it may be necessary for you to stop using MICAFUNGIN ADCO
- Rash or itching
- Fainting
- Severe reaction of the skin such as wheals, hives or welts, itching, redness of the skin, skin rash
- Stevens-Johnson syndrome (Skin disease)
- Toxic exfoliation of skin
- Inflammation and scaling of the skin

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

- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing
- These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- abnormal blood tests, neutropenia (decreased white blood cells), anaemia (decreased red blood cells)
- hypokalaemia (decreased potassium in the blood), hypomagnesaemia (decreased magnesium in the blood), hypocalcaemia (decreased calcium in the blood)

- headache
- phlebitis (swelling of veins)
- nausea (feeling sick), vomiting, diarrhoea, abdominal pain
- abnormal liver function tests
- rash
- fever, shivering

Less frequent side effects:

- abnormal blood tests, low levels of red blood cells, white blood cells and platelets
- eosinophilia (blood disorder - high levels of eosinophils in blood)
- hypersensitivity
- hyperhidrosis (excessive sweating affecting the palms, soles and armpits)
- hyponatraemia (decreased sodium in the blood), hyperkalaemia (decreased potassium in the blood), hypophosphataemia (decreased phosphates in the blood)
- anorexia (eating disorder)
- insomnia (inability to sleep), confusion, anxiety
- drowsiness or sleepiness, trembling, dizziness
- altered sense of taste
- abnormally rapid, irregular or slow heart rate
- sudden redness of skin
- high blood pressure, low blood pressure
- shortness of breath
- dyspepsia (painful, difficult or disturbed digestion)
- constipation
- liver inflammation, enlarged liver, increased liver enzymes, liver failure
- jaundice (yellowing of the skin or whites of the eyes caused by liver problems)
- severe reaction of the skin such as wheals, hives or welts, itching, redness of the skin, skin rash

- abnormal kidney function tests, kidney failure
- local pain and swelling at the injection site

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

Additional side effects in children and adolescents

Frequent side effects:

- thrombocytopaenia (decrease in blood platelets)
- tachycardia (increased hard rate)
- high or low blood pressure
- hyperbilirubinaemia (increased bile pigment in the blood), enlarged liver
- kidney failure, increased urea in the blood

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 MICAFUNGIN ADCO

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store MICAFUNGIN ADCO

Store all medicines out of reach of children.

Store at or below 25 ºC.

6. Contents of the pack and other information

What MICAFUNGIN ADCO contains

The active substance is Micafungin (as sodium salt).

Each 10 ml vial contains either 50 mg or 100 mg of micafugin (as sodium salt)

The other ingredients are:

- Lactose monohydrate
- Citric acid anhydrous
- Sodium hydroxide

What MICAFUNGIN ADCO looks like and contents of the pack

MICAFUNGIN 50 mg ADCO: white lyophilized cake or powder filled in a 10 ml Type I clear glass vial with a bromobutyl double slotted rubber stopper and an aluminium flip off seal with royal blue colour button.

MICAFUNGIN 100 mg ADCO: white lyophilized cake or powder filled in a 10 ml Type I clear glass vial with a bromobutyl double slotted rubber stopper and an aluminium flip off seal with red colour button.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road,

Aeroton, Johannesburg

2013

Tel: 011 494 8000

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MICAFUNGIN 100 mg ADCO: 55/20.2.2/0667