SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Fungizone Intravenous (Injection)

Read all of this leaflet carefully before you are given FUNGIZONE INTRAVENOUS.

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

1. WHAT FUNGIZONE INTRAVENOUS CONTAINS

The active substance is Amphotericin B 50 mg. FUNGIZONE Intravenous also contains sodium desoxycholate 41 mg with sodium phosphate 20,2 mg as a buffer.

The other ingredients are desoxycholic acid, disodium phosphate dodecahydrate, monosodium phosphate dihydrate, water for injection.

2. WHAT FUNGIZONE INTRAVENOUS IS USED FOR

Fungizone Intravenous is used to treat potentially life-threatening fungal infections.

3. BEFORE YOU ARE GIVEN FUNGIZONE INTRAVENOUS

You should not be given FUNGIZONE Intravenous:

If you are hypersensitive (allergic) to amphotericin B or any of the other ingredients of FUNGIZONE Intravenous.

Special care should be taken with FUNGIZONE Intravenous:

- If you are pregnant, tell your doctor before receiving FUNGIZONE Intravenous. It is not known whether amphotericin B is excreted in breast milk. You should not use FUNGIZONE Intravenous if you are pregnant or breast-feeding your baby.
- FUNGIZONE Intravenous is not recommended for paediatric use, but systemic fungal infections have been treated in pediatric patients without reports of unusual side effects.

Taking other medicines with FUNGIZONE Intravenous:

If you are taking / using other medicines on a regular basis, including complementary or traditional medicines, the use of FUNGIZONE Intravenous with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.
Inform your doctor about other medicines you may be taking or have recently taken including those obtained without a prescription.
This is especially important if you are taking:

- Anti-cancer medicines (e.g. cisplatin)
- Any medicines which affect your kidney function (e.g. gentamicin, vancomycin)
- Any muscle relaxants
- Any corticosteroids (e.g. beclamethasone)
- Any medicines to treat heart failure (e.g. digoxin)
- A medicine called flucytosine used to treat fungal infections.

If you have recently had a specific type of transfusion called a leukocyte transfusion, please tell your doctor.

4. HOW TO RECEIVE FUNGIZONE INTRAVENOUS

FUNGIZONE Intravenous will be given to you in hospital by a healthcare professional. If you have any concerns about the amount of medicine you have been given, please speak to the person who has given you the infusion for further advice.

Your doctor will give you the correct dose of FUNGIZONE Intravenous.

Your doctor will tell you how long your treatment with FUNGIZONE Intravenous will last. FUNGIZONE Intravenous will be given to you slowly through a drip into a vein (an infusion). This will usually take between 2 – 6 hours.

A test dose may be given before you start treatment with FUNGIZONE Intravenous. Several months of treatment is usually necessary to get rid of the infection completely.

5. POSSIBLE SIDE EFFECTS

FUNGIZONE Intravenous can cause side effects.

Not all side effects reported for FUNGIZONE Intravenous are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Treatment with FUNGIZONE Intravenous may affect your blood cells, kidneys, liver or heart. For this reason, your doctor will want to monitor all these things, during and after giving you FUNGIZONE Intravenous.

If you notice any of the following, contact your doctor **immediately**:

- Swelling of the face, lips or tongue
- Skin reactions including, sever rash and itching
- Difficulty breathing

All these may be signs of an allergic reaction.

There have been reports of blood disorders which may be characterized by fever, chills, sore throat, ulcers in the mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises. Tell your doctor **immediately** if you notice these symptoms.

FUNGIZONE Intravenous can cause kidney problems. If you notice that you are more thirsty, need to go to the toilet more frequently, or the volume of urine increases, tell your doctor **immediately**.

The most frequent side effects experienced with FUNGIZONE Intravenous are:

- High temperature (sometimes with shaking chills)
- Headache
- Loss of appetite, weight loss
- Feeling sick and being sick
- Pain in muscles and joints
- Generally feeling unwell
- Stomach cramps, indigestion
- Diarrhoea
- Pain at the injection site, with swollen veins
- A rare form of anaemia where there is a low level of red blood cells
- Kidney problems which may lead to abnormal urine production, kidney stones and imbalances of substances in the blood (e.g. potassium)

Less frequent side effects experienced with FUNGIZONE Intravenous are:

- Irregular heartbeat, sometimes severe
- Heart attack
- High or low blood pressure
- Hearing loss, ringing in the ears
- Blurred or double vision
- Short-lived spinning sensation (vertigo)
- Convulsions
- Altered mental state
- Flushing
- Liver failure
- Numbness, pain or tingling in the hands or feet
- Bloody stools or vomiting blood (may indicate bleeding from the stomach or gut)

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

6. STORING AND DISPOSING OF FUNGIZONE INTRAVENOUS

FUNGIZONE Intravenous in powder form should be stored in the refrigerator, between 2 - 8 °C protected against exposure to light. The concentrate, i.e. (5 mg amphotericin B per ml after reconstitution of the powder with 10 ml Sterile Water for Injection) may be stored, protected against exposure to light, at room temperature for 24 hours, or at refrigerator temperatures for one week with minimal loss of potency and clarity. Any unused material should then be discarded. Solutions prepared for intravenous infusion (0,1 mg or less amphotericin B per ml) should be used promptly after preparation and should be protected from light during administration. Any unused concentrate should be discarded.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

7. PRESENTATION OF FUNGIZONE INTRAVENOUS

FUNGIZONE Intravenous is supplied in clear vials as a sterile lyophilized powder providing 50 mg amphotericin B and 41 mg sodium desoxycholate with 20,2 mg sodium phosphate as a buffer.

8. IDENTIFICATION OF FUNGIZONE INTRAVENOUS

Injection: Dry: A yellow to orange, fine fluffy powder, or a dry cake.

Reconstituted product: A collodial dispersion practically free from visible evidence of contamination.

9. REGISTRATION NUMBER

A/20.1.7/0150

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

12 April 2019

*Authorised user of the ™ FUNGIZONE.