Dr. Reddy's Laboratories (Pty) Ltd.
ENGLISH Patient Information Leaflet:
CASFOLRED 50 & 70
(lyophilised powder for concentrate for solution for infusion)

SCHEDULING STATUS

S4

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM

CASFOLRED 50 (lyophilised powder for concentrate for solution for infusion)

CASFOLRED 70 (lyophilised powder for concentrate for solution for infusion)

Read all of this leaflet carefully before you start receiving CASFOLRED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- **CASFOLRED** 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 CASFOLRED CONTAINS

The active substance is caspofungin.

Each vial of **CASFOLRED 50** contains 55,5 mg of caspofungin acetate equivalent to 50 mg caspofungin.

Each vial of **CASFOLRED 70** contains 77,7 mg of caspofungin acetate equivalent to 70 mg caspofungin acetate.

The other ingredients of **CASFOLRED** are argon, mannitol, sucrose and water for injection.

Contains sugar (mannitol).

2. WHAT CASFOLRED IS USED FOR

CASFOLRED belong to a group of medicines called antifungal medicines.

CASFOLRED is used in the treatment of various fungal infections.

3. BEFORE YOU ARE ADMINISITERED CASFOLRED

You should not be administered with CASFOLRED if you:

- are hypersensitive (allergic) to caspofungin or any of the ingredients of **CASFOLRED.** (See "WHAT **CASFOLRED** CONTAINS").
- if you suffer from severe liver problems.

Take special care with CASFOLRED

Tell your doctor or healthcare professional before being given the injection if:

- you have a history of any allergic reactions including allergic skin reactions (See also "POSSIBLE SIDE EFFECTS").
- you suffer from liver problems.
- you are taking a medicine called ciclosporin (which is used to help prevent organ transplant rejection or to suppress your immune system), as your doctor may need to run extra blood tests during your treatment.

Use in children

CASFOLRED can be used in children and adolescents (at least 3 months of age and up through 17 years of age) for all the infection types described (see "WHAT **CASFOLRED** IS USED FOR"**)**.

CASFOLRED has not adequately been studied in infants under 3 months of age**.**

Receiving CASFOLRED with food and drink

There is no information to suggest that food and drink consumption affects the way **CASFOLRED** works.

Pregnancy and Breastfeeding

You should not receive **CASFOLRED** if you are pregnant or planning to be pregnant.

You should not receive **CASFOLRED** if you are breastfeeding your baby.

If you are pregnant or plan to become pregnant or are breastfeeding your baby consult your doctor, pharmacist or other health care professional for advice before receiving **CASFOLRED.**

Driving and using machinery

There is no information to suggest that **CASFOLRED** affects your ability to drive or operate machinery.

Important information about some of the ingredients of CASFOLRED

CASFOLRED contains sucrose and mannitol which are types of sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using **CASFOLRED.**

CASFOLRED contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not use **CASFOLRED.**

CASFOLRED contains mannitol which, on rare occasions, may cause hypersensitivity reactions.

Using other medicines with CASFOLRED

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).

If you are being administered with **CASFOLRED** you can continue taking other medicines for your other medical conditions without interruption. Your doctor will determine if any adjustments should be made to your other medications.
In particular, tell your doctor if you are using other medicines and especially if any of the following medicines are:

- ciclosporin and tacrolimus (are medicines used to help prevent organ transplant rejection or to suppress your immune system) as your doctor may need to run extra blood tests during your treatment.
- some HIV medicines such as efavirenz or nevirapine.
- phenytoin or carbamazepine (are medicines used for the treatment of seizures).
- dexamethasone (medicine called a steroid).
- rifampicin (a medicine called an antibiotic).

4. HOW TO USE CASFOLRED

CASFOLRED will always be prepared and given to you by a healthcare professional.

CASFOLRED will be given once a day by slow intravenous infusion over approximately 1 hour.

Your doctor will decide on the most suitable treatment for you including:

- the correct dose
- how often and for how long you should be treated and
- whether you should also receive other medicines with **CASFOLRED** or not.

If you have the impression that the effect of **CASFOLRED** is too strong or too weak, tell your doctor or another healthcare professional.

Do not stop treatment early without discussing this with your doctor.

If you are receiving more CASFOLRED than you should

The treatment schedule and dose will be decided by your doctor, who will monitor your response. If you are concerned that you have been given too much **CASFOLRED**, contact your doctor or another healthcare professional immediately.

If you forget to receive CASFOLRED for any reason, discuss this with your doctor or another healthcare professional immediately.

If you stop receiving CASFOLRED

Discuss the effects of stopping treatment with **CASFOLRED** if you choose to do so with your doctor.

5. POSSIBLE SIDE EFFECTS

CASFOLRED can have side effects.

Not all side effects reported for **CASFOLRED** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **CASFOLRED,** please consult your doctor, pharmacist or other health care professional for advice.

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

- swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing', throat tightness.
- shortness of breath and wheezing.
- rash, hives (raised bumps), blisters or itching.
- allergic reactions can happen in patients taking **CASFOLRED** even after only one dose.

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

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 harder and faster.
- difficulty breathing.
- signs of recurrent 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.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decrease in haemoglobin (decreased oxygen carrying substance in the blood) and white blood cells, increased number of eosinophils which are a type of white blood cells (picked up in blood tests).

- decrease in blood albumin (a type of protein) in your blood (picked up in blood tests).
- increase in liver enzymes, decrease in potassium (hypokalaemia), magnesium and phosphorus, increase in blood sugar levels and phosphorus (picked up in blood tests).
- headache.
- increased heart rate (tachycardia).
- when your skin becomes warm and red (flushing), decreased in blood pressure where you may feel dizzy or faint, have cold and clammy skin, feel tired, thirsty, fast but shallow breathing (hypotension).
- inflammation of the veins (phlebitis).
- shortness of breath (dyspnoea).
- feeling sick (nausea), "throwing up" (vomiting), runny tummy (diarrhoea).
- increase in liver enzymes (picked up in blood tests).

  rash, itching (pruritus), sweating (hyperhidrosis), redness of the skin (erythema).
- joint pain (arthralgia).
- fever (pyrexia), chills, itching at the infusion/injection site.

Less frequent side effects:

- you may feel tired, look pale, a feeling as though your heart is racing, be short of breath, and/or worsening of heart problems (anaemia), you may not have enough blood cells called platelets which may cause bleeding (thrombocytopaenia), blood is unable to clot properly (coagulopathy), decrease in white blood cells (leukopaenia), increase or decrease in types of white blood cells, increase or decrease in blood cells that help with clotting (picked up in blood tests).
- too much fluid in the blood (fluid overload), decrease in magnesium

(hypomagnesaemia), loss of appetite (anorexia), increase sugar levels (hyperglycaemia), decrease in calcium (hypocalcaemia), body produces high amount of acid (metabolic acidosis).

- feeling anxious, a state of mental confusion (disorientation), problems sleeping (insomnia).
- feeling dizzy, problems with your sense of taste (dysgeusia), tingling or pricking ("pins and needles") (paraesthesia), sleepiness/drowsiness (somnolence), shaking (tremor), decreased sense of touch (hypoaesthesia).
- yellowing of part of the eye (ocular icterus), vision blurred, swelling of the eyelid (eyelid oedema), increased tearing (lacrimation).
- your heart beats too hard or too fast (palpitations), increase in heart rate (tachycardia), problem with the rate of rhythm of the heart beat (arrhythmia), heart failure.
- inflammation of a vein that's caused by a blood clot (thrombophlebitis), hot flushes, high blood pressure (hypertension), low blood pressure) hypotension.
- stuffy nose (nasal congestion), pain or discomfort in the throat (pharyngolaryngeal pain), rapid breathing (tachypnoea), difficulty in breathing (bronchospasm), cough, shortness of breath that will awaken you after 1 to 2 hours of sleep (dyspnoea paroxysmal nocturnal), body doesn't get enough oxygen (hypoxia), clicking, rattling, or crackling noises that may be made by one or both of your lungs (rales), wheezing.
- stomach pain and or discomfort (abdominal pain), dry mouth, indigestion (dyspepsia), air or fluid in the stomach causing it to expand (abdominal distension), accumulation of fluid in the stomach (ascites), hard to pass stools (constipation), difficulty in swallowing (dysphagia), excessive gas (flatulence).

- reduction of stoppage of bile flow (cholestasis), abnormally enlarged liver (hepatomegaly), increase in a substance called bilirubin (hyperbilirubinaemia), yellowing of the skin (jaundice), abnormal liver function, damage to the liver caused by a medicine (hepatotoxicity), increase in liver enzymes.
- hypersensitivity reaction which shows as a rash(erythema multiforme), different types of rashes, "hives" (urticaria), inflammation of the skin (dermatitis allergic),generalised itching (pruritus), skin lesion.
- back pain, pain in the hands and feet, bone pain, muscle weakness, muscle pain (myalgia).
- kidney failure.
- pain, pain at the site of the injection, reddening and swelling of the skin around the injection site, hardening of the area around the injection site, inflammation of the vein around the injection site, feeling tired (fatigue), feeling cold, feeling hot, swelling of legs and feet (oedema peripheral), tenderness, chest discomfort, chest pain, swelling of the face (face oedema), feeling of body temperature change, induration, infusion site extravasation, infusion site irritation, infusion site phlebitis, infusion site rash, infusion site urticaria, injection site erythema, injection site oedema, injection site pain, injection site swelling, malaise, oedema.
- changes in various blood and urine laboratory tests.
- increase in calcium and a type of white blood cell which can be picked up in blood tests.

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

6. STORING AND DISPOSING OF CASFOLRED

Unopened vials should be stored at 2 to 8 °C.

Although chemical and physical stability of reconstituted/diluted solutions has been demonstrated for 24 hours at 25 °C and 48 hours at 2 to 8 °C from a micro biological point of view, the product 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 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Once **CASFOLRED** has been prepared by a trained healthcare professional, it should be used straight away. This is because it does not contain any ingredients to stop the growth of bacteria.

Do not use this medicine after the expiry date.

Keep this medicine out of the sight and reach of children.

Do not dispose medicines in drains or sewerage systems (e.g. toilets).

Return all unused and expired medicines to your pharmacist.

7. PRESENTATION OF CASFOLRED

CASFOLRED 50 is supplied in 10 ml USP type – I clear glass tubular Lyo vials with 20 mm neck diameter and 20 mm grey bromobutyl rubber stoppers and sealed with 20 mm aluminium flip off seals.

CASFOLRED 70 is supplied in 10 ml USP type – I clear glass tubular Lyo vials with 20 mm neck diameter and 20 mm grey bromobutyl rubber stoppers and sealed with 20 mm aluminium flip off seals.

The glass vial is packed in a printed outer carton along with the package insert.

8. IDENTIFICATION OF CASFOLRED

Unopened vials

Each vial of **CASFOLRED** contains a white to off white lyophilised cake/powder.

Reconstituted vials

Clear solution, essentially free from visible particles.

Diluted product for infusion

Clear solution, essentially free from visible particles.

9. REGISTRATION NUMBERS

CASFOLRED 50: 50/20.2.2/0945

CASFOLRED 70: 50/20.2.2/0946

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Dr. Reddy's Laboratories (Pty) Ltd.

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1 Sandton Drive

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2196

11. DATE OF PUBLICATION

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