

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

CANCIDAS® 50 mg Lyophilised Powder For Solution For Infusion

CANCIDAS® 70 mg Lyophilised Powder For Solution For Infusion

Caspofungin

Read all of this leaflet carefully before you start using CANCIDAS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CANCIDAS has been prescribed for you personally or for your child and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours or those of your child.

1. WHAT CANCIDAS CONTAINS

- The active substance is Caspofungin. Each vial of CANCIDAS 50 mg contains 50 mg of the active substance, Caspofungin anhydrous free base, equivalent to 55,5 mg of Caspofungin acetate. Each vial of CANCIDAS 70 mg contains 70 mg of the active substance, Caspofungin anhydrous free base, equivalent to 77,7 mg of Caspofungin acetate.
- The other ingredients are glacial acetic acid, mannitol, sodium hydroxide, sucrose and water for injection.

- Contains sugar (sucrose and mannitol).

2. WHAT CANCIDAS IS USED FOR

CANCIDAS is an antifungal medicine that interferes with the production of a component (glucan polysaccharide) of the fungal cell wall that is necessary if the fungus is to continue living and growing. Fungal cells exposed to CANCEIDAS have incomplete or defective cell walls, making them fragile and unable to grow.

Why has my doctor prescribed CANCEIDAS?

Your doctor has prescribed CANCEIDAS for one of several reasons described below.

- A fungal infection caused by organisms called *Candida*, which may occur in the bloodstream and can, in some cases, spread to deep organs such as the lining of the abdomen (peritonitis), the heart, the kidneys, the liver, bones, muscles, joints, spleen or eyes. Fever and chills that do not respond to antibacterial therapy are the most common symptoms of this type of infection.
- Another type of fungal infection caused by *Candida*, which occurs in your mouth, your throat and/or your oesophagus (the food tube that connects your mouth to your stomach). Sometimes the infection in the mouth and throat is referred to as “thrush”. This disease may cause difficult or painful swallowing and can often be seen as yellow-white patchy areas or yellow-white raised patchy areas in the mouth and throat.
- A fungal infection in your nose, nasal sinuses or lungs. In this case, your doctor has prescribed CANCEIDAS because other antifungal treatments have not been working as well as expected or because the other antifungal treatments are causing side effects. This infection is caused by organisms called *Aspergillus*.
- Persistent fever due to infection may occur following chemotherapy or other medical treatments or conditions that lower the body's resistance to disease by lowering counts of certain white blood cells. If the fever is not reduced by treatment with an antibiotic, your doctor may suspect that you have fungal infection.

Use in children

CANCIDAS has been approved for use in children and adolescents (at least 3 months of age and up through 17 years of age) for all the infection types described above. The dose used in paediatric patients may differ from the dose used in adult patients.

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

3. BEFORE YOU ARE GIVEN CANCIDAS

You should not receive CANCIDAS:

- If you are hypersensitive (allergic) to Caspofungin or any of its components.

What should I tell my doctor [or pharmacist] before receiving CANCIDAS?

Life-threatening allergic reactions have been reported rarely during administration of CANCIDAS. Possibly histamine-mediated signs or symptoms have been reported, including rash, swelling of the face and/or lips, itching, sensation of warmth or trouble breathing. CANCIDAS may also cause serious skin adverse reactions including skin peeling, mucous membrane sores, hives, or large areas of peeling skin. Tell your doctor or pharmacist promptly about these or any other unusual signs or symptoms.

Tell your doctor [or pharmacist] about any medical conditions you have or have had, and about any allergies.

Take special care with CANCIDAS

Use in the elderly

No dose adjustment is necessary for the elderly.

Use in patients with kidney problems

No dosage adjustment is necessary for patients with reduced kidney function.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established.

- CANCIDAS has not been studied in pregnant women. CANCIDAS should therefore not be used in pregnancy.
- Women receiving CANCIDAS should not breastfeed.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using of machinery

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

Using other medicines with CANCIDAS

Most patients being administered CANCIDAS will continue to receive medications for their other medical conditions without interruption. Your doctor will determine if any adjustments should be made to your other medications. Because of a possible interaction between CANCIDAS and ciclosporin you should tell your doctor if you are taking ciclosporin.

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

In addition, you should always tell your doctor about all other medications that you are taking or plan to take, including those obtained without a prescription. It is particularly important for your doctor to know if you are taking certain anti-HIV medicines (including efavirenz or nevirapine), the anti-seizure (epilepsy) medications phenytoin and carbamazepine, the steroid dexamethasone, the antibiotic rifampicin and the immunosuppressant tacrolimus.

4. HOW TO USE CANCIDAS

How should CANCIDAS be given?

You will not be expected to give yourself CANCIDAS. It will be given to you by a person who is qualified to do so. CANCIDAS should be administered once daily by slow intravenous infusion of approximately 1 hour. Your doctor will determine the duration of your treatment and how much CANCIDAS you will receive each day.

How long do I need to receive CANCIDAS?

It is very important that you continue to receive CANCIDAS for as long as your doctor prescribes it. Your doctor will let you know when you may stop receiving CANCIDAS.

If you are given more CANCIDAS more than you should

The treatment schedule and dosage will be set by your doctor, who will monitor your response and condition. If you are concerned that you may have been given too much CANCIDAS, contact your doctor or another healthcare professional immediately.

If you forget to have CANCIDAS administered to you

The treatment schedule and dosage will be set by your doctor, who will monitor your response and condition. If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

Effects when treatment with CANCIDAS is stopped

There are no known withdrawal symptoms. None of the components of CANCIDAS have been shown to be addictive.

5. POSSIBLE SIDE EFFECTS

CANCIDAS may have side effects.

The most common medication-related undesirable effects in adults are fever and vein irritations at the infusion site (itching, redness, swelling or clotting). Other reported medication-related undesirable effects in adults include: Headache, bone pain, chills, sweating, nausea, diarrhoea, vomiting, rash, skin redness, itching, trouble breathing, swelling of the hands, ankles or feet, impaired liver function and alterations in some laboratory blood tests.

The most common medication-related undesirable effects in children and adolescents are fever, rash and headache. Other reported medication-related undesirable effects in children and adolescents include: Pain at the catheter site, chills, rapid heartbeat, flushing, itching, low blood pressure and alterations in some laboratory blood tests.

Life-threatening allergic reactions have also been reported rarely during administration of CANCIDAS. Other side effects may also occur rarely; and, as with any prescription medication, some side effects

may be serious. Ask your doctor or pharmacist for more information. Tell your doctor [or pharmacist] promptly about these or any other unusual symptoms.

Additionally, while the medicine has been on the market, the following have been reported:

- Rash, skin peeling, mucous membrane sores, hives, large areas of peeling skin.

Your doctor or healthcare professional has a more complete list. Tell your doctor or healthcare professional promptly about these or any other unusual symptoms.

Not all side effects reported for CANCIDAS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CANCIDAS, please inform your doctor, pharmacist or other healthcare professional.

HOW CAN I LEARN MORE ABOUT CANCIDAS AND THE CONDITION FOR WHICH IT WAS PRESCRIBED?

You may obtain further information from your doctor or other healthcare professionals who have more detailed information about the product and your condition.

6. STORING AND DISPOSING OF CANCIDAS

How long should CANCIDAS be kept?

This medicine should not be used after the month and year following EXP.: on the container.

How should CANCIDAS be stored?

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

Reconstituted CANCIDAS should be used immediately because it does not contain any preservatives to prevent bacterial contamination. Only a trained healthcare professional who has access to the complete directions provided with each vial can properly prepare this medication for use.

Do not freeze.

Store all medicines out of reach of children.

7. PRESENTATION OF CANCIDAS

CANCIDAS 50 mg and 70 mg lyophilised powder for solution for infusion are supplied in 10 ml clear glass vials.

8. IDENTIFICATION OF CANCIDAS

Diluted product for infusion

Clear solution essentially free from visible particles.

Unopened vials

Each vial of CANCIDAS contains a solid white to off-white cake.

Reconstituted CANCIDAS in vials

Clear solution essentially free from visible particles.

Diluted product for infusion

Clear solution essentially free from visible particles.

9. REGISTRATION NUMBERS

CANCIDAS 50 mg: 37/20.2.2/0544

CANCIDAS 70 mg: 37/20.2.2/0545

10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

South Africa

Tel. No.: 011 655 3000

11. DATE OF PUBLICATION

Date on the registration certificate: 12 November 2004

Date of the most recently revised as approved: 14 May 2017

WPPI-MK0991-IV-102015, 102016