

CANCIDAS(R)

for intravenous infusion

Caspofungin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CANCIDAS. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using CANCIDAS against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What CANCIDAS is used for

CANCIDAS is used to treat the following fungal infections:

- * Invasive candidiasis, including candidaemia
- * Oesophageal candidiasis
- * Invasive aspergillosis, when other antifungal treatments have not worked or when other antifungal treatments have not been tolerated.

Also, your doctor may suspect that you or your child have a fungal infection in the following situation, and prescribe CANCIDAS to treat it.

- * Chemotherapy or other medical treatments or conditions can lower the body's resistance to disease by lowering counts of certain white blood cells. If you have persistent fever following chemotherapy or under other conditions as noted above, and your fever is not reduced by treatment with an antibiotic, you may have a fungal infection.

Candidiasis is an infection caused by a fungus (yeast) called candida. Invasive candidiasis is a serious type of candidiasis which occurs in your bloodstream (referred to as candidaemia), or in tissues or organs such as the lining of the abdomen (peritonitis), the heart, kidneys, liver, bones, muscles, joints, spleen, or eyes.

Candidiasis can also occur in your food pipe, also known as the oesophagus (oesophageal candidiasis). It may cause difficulty or pain when swallowing.

Invasive aspergillosis is an infection caused by a fungus, called aspergillus (as-pur-jilus). Most of these infections begin in the respiratory tract (in the nose, sinuses, or lungs) because the spores of the fungus are usually present in the air we breathe. The spores are harmless in most healthy people due to the body's natural ability to fight disease.

However, invasive aspergillosis can be serious in certain circumstances as it can spread to other tissues and organs. Groups of people who are at increased risk of invasive aspergillosis include those who have

poor immune systems, such as people with organ transplants, certain cancers and HIV/AIDS.

How CANCIDAS works

CANCIDAS belongs to a group of medicines called echinocandins.

It works by interfering with the production of a component of the fungal cell wall that is necessary for the fungus to continue living and growing. Fungal cells exposed to CANCIDAS have incomplete or defective cell walls, making them fragile and unable to grow.

Your doctor may have prescribed CANCIDAS for another reason.

Ask your doctor if you have any questions about why CANCIDAS has been prescribed for you or your child.

The safety and effectiveness of CANCIDAS in children younger than 3 months of age have not been established.

Before you are given CANCIDAS

When you must not be given it

Do not use CANCIDAS if you or your child have an allergy to CANCIDAS or any of the ingredients listed at the end of this leaflet

Do not use CANCIDAS if you are breast-feeding or intend to breast-feed

CANCIDAS is not recommended for use while breast-feeding. It is not known whether it passes into breast milk in humans.

Before you are given it

Tell your doctor if you or your child:

1. are pregnant

Like most medicines, CANCIDAS is generally not recommended during pregnancy. However, if there is a need to consider using CANCIDAS during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.

- 2. have or have had any medical conditions, especially liver disease**
- 3. have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**

If you have not told your doctor about any of the above, tell them before you or your child are given CANCIDAS.

Taking other medicines

Tell your doctor if you or your child are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and CANCIDAS may interfere with each other. These include:

- * tacrolimus, used to help prevent organ transplant rejection or to treat certain problems with the immune system
- * efavirenz and nevirapine, used to treat HIV infection
- * phenytoin and carbamazepine, used to treat epilepsy and/or convulsions

- * rifampicin, an antibiotic used to treat tuberculosis and other infections
- * dexamethasone, a corticosteroid medicine used to treat inflammation

These medicines may be affected by CANCIDAS, or may affect how well it works. You or your child may need different amounts of your medicine, or you may need to take different medicines.

CANCIDAS should be used with caution with cyclosporin (a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system) as the combination may cause abnormalities in some tests of your liver function. In addition, using the two medicines together may increase the level of CANCIDAS in your body.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given CANCIDAS.

How CANCIDAS is given

CANCIDAS is given as a slow injection into a vein.

CANCIDAS must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you or your child will receive CANCIDAS. This depends on the condition and other factors, such as liver function. No dose adjustment is necessary if you are elderly or if you have reduced kidney function.

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you or your child do not feel well while being given CANCIDAS.

CANCIDAS helps most people with invasive or oesophageal candidiasis or invasive aspergillosis, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Tell your doctor or nurse if you or your child notice any of the following and they worry you:

- * vein irritations where you had the injection, including redness, swelling, or clotting
- * headache, dizziness, pain, chills
- * nausea, vomiting
- * diarrhoea, stomach pain
- * flushing, tremor, sweating
- * high blood pressure
- * aching muscles, joints or bones
- * difficulty sleeping
- * swelling of the hands, ankles or feet

These are the more common side effects of CANCIDAS. For the most part, these have been mild.

Tell your doctor or nurse immediately if you or your child notice any of the following:

- * fever that has developed or worsened after starting treatment with CANCIDAS
- * signs of anaemia such as tiredness, being short of breath, looking pale
- * skin rash or itching

- * pinkish, itchy swellings on the skin, also called hives or nettle rash
- * difficulty breathing, shortness of breath, or faster rate of breathing than usual
- * swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- * fast heart rate
- * numbness or tingling in fingers or toes

You or your child may need urgent medical attention. If you have some of these effects, you may be having a serious allergic reaction to CANCIDAS. Life-threatening allergic reactions have been reported.

Liver problems can also occur and can be serious.

Other side effects not listed above may also occur in some patients. Tell your doctor if you or your child notice any other effects.

Storage

CANCIDAS will be stored in the pharmacy or on the ward.

It is kept in a refrigerator where the temperature stays between 2-8 degrees C.

Product Description

What it looks like

CANCIDAS comes as a white to off-white powder in a glass vial.

Ingredients

Active ingredient:

- * CANCIDAS 50 mg - caspofungin 50 mg (55.5 mg as the acetate salt) per vial

- * CANCIDAS 70 mg - caspofungin 70 mg (77.7 mg as the acetate salt) per vial

Inactive ingredients:

- * sucrose
- * mannitol
- * glacial acetic acid
- * sodium hydroxide

Supplier

CANCIDAS is supplied in Australia by:

Merck Sharp & Dohme (Australia)
Pty Limited
A.C.N. 000 173 508
54-68 Ferndell Street
SOUTH GRANVILLE NSW 2142

This leaflet was prepared in May 2009

Australian Register Number:
CANCIDAS 50 mg - AUST R 76531
CANCIDAS 70 mg - AUST R 76530

WPPI-CAN-IV-012008