

PART III: CONSUMER INFORMATION

Pr **CANCIDAS[®]**

casposfungin acetate for injection

This leaflet is part III of a three-part "Product Monograph" published when CANCIDAS[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you or your child everything about CANCIDAS[®]. Contact your doctor or pharmacist if you or your child have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor has prescribed CANCIDAS[®] to treat one of several types of fungal infections described below.

- A serious fungal infection called invasive candidiasis. The infection is caused by fungal (yeast) cells called *Candida*. These yeast cells are normally found in the digestive tract, and do not cause an infection unless they enter the bloodstream (in which case the infection is referred to as candidemia) or other tissues or organs, such as the lining of the abdomen (peritonitis), the kidneys, the liver, bones, muscles, joints, spleen, or eyes. Persons at high risk for invasive candidiasis include surgical patients and those whose immune systems are deficient.
- Fungal infections of the mouth, back of the throat, and the food tube connecting the mouth to the stomach. These infections are called oropharyngeal candidiasis (mouth and back of the throat) or esophageal (food tube) candidiasis. The infection is also caused by *Candida*. Healthy individuals usually have *Candida* in their mouth and throat without any ill effects. An infection occurs when the body's resistance to disease is lowered.
- A serious fungal infection called invasive aspergillosis. Invasive aspergillosis is a serious infection of the nose, nasal sinuses, and lungs. This infection may spread to other parts of the body. This kind of infection is caused by a number of common fungi found in the environment called *Aspergillus*. Most *Aspergillus* fungal infections begin in the respiratory system (in the nose, sinuses, or lungs) because the spores of the fungus are found in the air we breathe every day. In most healthy individuals, the natural ability to fight disease destroys the spores and removes them from the body. Some medical conditions lower the body's resistance to diseases. Also,

certain medications prescribed for patients who are organ or bone marrow recipients lower the body's resistance to diseases. These are the patients who are most likely to develop these infections.

Also, your doctor may suspect that you 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.

What it does:

CANCIDAS[®] is an antifungal drug 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 CANCIDAS[®] have incomplete or defective cell walls, making them fragile and unable to grow.

When it should not be used:

Who should not receive CANCIDAS[®]?

CANCIDAS[®] should not be administered to you if you are allergic to any of its components (see "What the important nonmedicinal ingredients are").

Use in children and Adolescents:

CANCIDAS[®] has been approved for use in children > 12 months of age and adolescents for all the infection types described above. The dose used in pediatric patients may differ from the dose used in adult patients.

What the medicinal ingredient is:

Casposfungin acetate

What the important nonmedicinal ingredients are:

Glacial acetic acid
Mannitol
Sodium hydroxide
Sucrose

This is a complete listing of all nonmedicinal ingredients.

What dosage forms it comes in:

Powder for injection, 50, 70 mg vials/cartons

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions:

The use of CANCIDAS[®] and cyclosporine at the same time is not recommended

Use in pregnancy and breast-feeding:

CANCIDAS[®] has not been studied in pregnant women. CANCIDAS[®] should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Women receiving CANCIDAS[®] should not breast-feed.

Use in patients with Hepatic Insufficiency:

Some patients with liver problems may require a dosage adjustment. Be sure to tell you doctor if you have had or now have liver problems.

BEFORE you use CANCIDAS[®] talk to your doctor or pharmacist if:

- You are taking cyclosporine
- 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 drugs (including efavirenz or nevirapine), the antiseizure (epilepsy) medications phenytoin and carbamazepine, the steroid dexamethasone, the antibiotic rifampin, and the immunosuppressant tacrolimus.
- You have liver problems
- You are pregnant
- You are breast feeding
- You are allergic to any component of CANCIDAS[®]

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CANCIDAS[®] include

- Carbamazepine
- Cyclosporine
- Dexamethasone
- Efavirenz
- Nevirapine
- Phenytoin
- Rifampin
- Tacrolimus

PROPER USE OF THIS MEDICATION

Usual Adult dose:

The treatment schedule and dosage will be set by your doctor, who will monitor your response and condition. CANCIDAS[®] should be administered once daily by slow intravenous infusion of approximately 1 hour.

A single 70 mg loading dose should be administered on Day 1, followed by 50 mg daily thereafter.

If you are treated for fungal infections of the mouth, back of the throat, and the food tube connecting the mouth to the stomach, 50 mg should be administered on Day 1 and daily thereafter.

Overdose:

If you are concerned that you may have been given too much CANCIDAS[®], contact your doctor, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

If you are concerned that you may have missed a dose, contact your doctor immediately.

No dosage adjustment is necessary for the elderly.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Anemia		√	
	Liver problems (yellowing of the skin)		√	
	Swollen veins (phlebitis/thrombophlebitis)	√		
Uncommon	Serious allergic reaction and symptoms such as severe rash, itching, swelling of hands and feet, swelling of face and lips, trouble breathing			√

Any medicine may have unintended or undesirable effects, so-called 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, pain, bone pain, chills, rapid heartbeats, sweating, nausea, diarrhea, 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 been reported rarely during administration of CANCIDAS[®] and symptoms may include swelling of the face, lips and throat, difficulty in breathing, rash, itching, or sensation of warmth. If any combination of these symptoms occurs contact your doctor immediately.

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.

This is not a complete list of side effects. For any unexpected effects while taking CANCIDAS[®] contact your doctor or pharmacist.

HOW TO STORE IT

Unopened vials of CANCIDAS[®] should be stored refrigerated at 2°C 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-877-428-8675, or
 - Mail to: Merck Canada Inc.
P.O. Box 1005
Pointe-Claire – Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594.

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