PART III: CONSUMER INFORMATION

PRERAXIS®
Anidulafungin

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

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:
ERAXIS belongs to a group of medicines called echinocandins. These medicines are used to treat serious fungal infections.
ERAXIS is prescribed to treat a type of fungal infection called invasive candidiasis (including candidemia). The infection is caused by fungal cells (yeasts) called *Candida*.

What it does:
Fungal cells exposed to ERAXIS have incomplete or defective cell walls making them fragile or unable to grow, thereby killing the cells and reducing the infection.

When it should not be used:
If you are allergic (hypersensitive) to anidulafungin, other echinocandins, or any of the other ingredients of ERAXIS (Fructose, Mannitol, Polysorbate 80, Tartaric acid, Sodium hydroxide or Hydrochloric acid).

What the medicinal ingredient is:
The active ingredient is anidulafungin.

What the important non-medicinal ingredients are:
Fructose, Mannitol, Polysorbate 80, Tartaric acid, Sodium hydroxide (for pH-adjustment), Hydrochloric acid (for pH-adjustment)

What dosage form it comes in:
ERAXIS is marketed as a carton containing 1 vial of 100 mg powder for solution for infusion.

WARNINGS AND PRECAUTIONS

BEFORE you use ERAXIS talk to your doctor or pharmacist:

- If you have been told by your doctor that you have an intolerance to some sugars. Patients with rare hereditary problems of fructose intolerance should not take this medicine. This medicinal product contains fructose.
- If you become pregnant while taking ERAXIS: ERAXIS should not be taken during pregnancy, unless indicated by your doctor. Effective contraception should be used in women of childbearing potential.
- If you are breast-feeding or planning to breast feed . You and you doctor will decide whether you should take this medication or not while breastfeeding or whether you should discontinue breastfeeding.
- If you have any allergies to this drug or its ingredients or components of the container.
- If you have liver problems.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is not expected that ERAXIS will interact with other medications or that any adjustments will be necessary to other medicines you may be taking. However, do not start or stop any other medications without your doctor or pharmacist's approval.

PROPER USE OF THIS MEDICATION

ERAXIS will always be prepared and given to you by a doctor or a healthcare professional.

Usual adult dose:
ERAXIS should be administered once a day, by slow infusion into your vein over approximately 1.5 to 3 hours. The treatment starts with a loading dose of 200 mg on the first day, then with subsequent daily maintenance dose of 100 mg.

ERAXIS should not be given to patients under 18 years of age.

Your doctor will determine the duration of your treatment and how much anidulafungin you will receive each day, and will monitor your response and condition.

Overdose:
Your doctor will monitor your response and condition to determine what ERAXIS treatment is needed. However, if you are concerned that you may have been given too much ERAXIS, tell your doctor or another healthcare professional immediately.

Missed Dose:
As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However tell your doctor or pharmacist if you think that a dose has been forgotten.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ERAXIS can cause side effects, although not everybody gets 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	-Hypokalemia (low potassium levels) and symptoms such as muscle weakness, and cramping, irregular heart beat, frequent urination		√	
Uncommon	- High blood pressure	√		
	-Liver problems (hepatitis) with symptoms such as persistent abdominal pain, nausea, Vomiting		√	√
	- Anaphylactic (allergic) reactions with symptoms such as rash, hives, low blood pressure, fainting, swelling of mouth, throat and extremities, weakness, difficulty in breathing		√	

• A common effect is diarrhea.
• Uncommon side effects include headache, rash, itching, flushing, eye pain, infusion site reaction
If these reactions become troublesome, contact your doctor

This is not a complete list of side effects. For any unexpected effects while taking* ERAXIS*, contact your doctor or pharmacist.

HOW TO STORE IT

Unreconstituted vials of ERAXIS are stored in a refrigerator (2-8°C). Do not freeze.

Keep out of the reach and sight of children.
Do not use ERAXIS after the expiry date which is stated on the label.

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 to 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 1908C
    Ottawa, ON K1A 0K9

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

***NOTE:* Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.**

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.pfizer.ca or by contacting the sponsor, Pfizer Canada ULC, at 1-800-463-6001 (Medical Information).

This leaflet was prepared by Pfizer Canada ULC

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