

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrERAXIS®

Anidulafungin

Read this carefully before you start taking **ERAXIS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ERAXIS**.

What is ERAXIS used for?

- 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*.

How does ERAXIS work?

ERAXIS belongs to a group of medicines called echinocandins. These medicines are used to treat serious fungal infections.

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.

What are the ingredients in ERAXIS?

Medicinal ingredients: anidulafungin

Non-medicinal ingredients: Fructose, Mannitol, Polysorbate 80, Tartaric acid, Sodium hydroxide (for pH-adjustment), Hydrochloric acid (for pH-adjustment)

ERAXIS comes in the following dosage forms:

ERAXIS is marketed as a carton containing 1 vial of 100 mg powder for solution for infusion.

Do not use ERAXIS if:

- If you are allergic (hypersensitive) to anidulafungin, other echinocandins, or any of the other ingredients of ERAXIS. See “What are the ingredients in ERAXIS?” section, above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ERAXIS. Talk about any health conditions or problems you may have, including if 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.
- are pregnant or think you might be pregnant while taking ERAXIS. It is not known how ERAXIS will affect your baby. Your healthcare professional will determine if the benefits outweigh the risks for you and your baby. You should use effective contraception while taking ERAXIS.
- are breast-feeding or planning to breast feed. You and your doctor will decide whether you should

take this medication or not while breastfeeding or whether you should discontinue breastfeeding.

- you have liver problems.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take ERAXIS:

- ERAXIS will be prepared and given to you by your healthcare professional.
- ERAXIS is given by slow infusion into your vein over approximately 1.5 to 3 hours.
- Your doctor will determine your dose and how long you should take ERAXIS based on your condition. Overall antifungal treatment should continue for at least 14 days after the last positive test.

Usual dose:

Adults:

- On the first day, you will receive a single dose of 200 mg.
- Each day afterwards, you will receive 100 mg daily.

Children (Older than 1 month old):

- Your child's dose will be determined by their weight.
- On the first day, your child will receive a single dose of 3 mg/kg (up to a maximum dose of 200 mg).
- Each day afterwards, they will receive 1.5 mg/kg daily (up to a maximum dose of 100 mg).

Overdose:

If you think you, or a person you are caring for, have taken too much ERAXIS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

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.

What are possible side effects from using ERAXIS?

These are not all the possible side effects you may have when taking ERAXIS. If you experience any side effects not listed here, tell your healthcare professional.

- A common effect is diarrhea.

- Uncommon side effects include headache, rash, itching, flushing, eye pain, infusion site reaction

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypokalemia (low potassium levels) and symptoms such as muscle weakness, and cramping, irregular heartbeat, 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		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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

Reconstituted solution may be stored at 15-30°C for up to 24 hours.

Keep out of reach and sight of children.

Do not use ERAXIS after the expiry date which is stated on the label.

If you want more information about ERAXIS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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