Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Anidulafungin
Lyophilized Powder for Reconstitution for Infusion
ERAXIS®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Eraxis (Anidulafungin) is and what it is used for

Eraxis (Anidulafungin) contains the active substance anidulafungin to treat a type of fungal infection of the blood or other internal organs called invasive candidiasis. The infection is caused by fungal cells (yeasts) called *Candida*.

It is used for the following indications:

Treatment of invasive candidiasis, including candidemia, in adult patients
Treatment of esophageal candidiasis, in adult patients

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2. What you need to know before you take Eraxis (Anidulafungin)

Do not take Eraxis (Anidulafungin)

- if you are allergic to anidulafungin, other echinocandins, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Eraxis (Anidulafungin).

Your doctor may decide to monitor you
- for liver function more closely if you develop liver problems during your treatment
- for signs of an allergic reaction such as itching, wheezing, blotchy skin
- for signs of an infusion–related reaction which could include a rash, hives, itching, redness
- for shortness of breath/breathing difficulties, dizziness or lightheadedness

Other medicines and Eraxis (Anidulafungin)

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

The effect of Eraxis (Anidulafungin) in pregnant women is not known. Therefore, Eraxis (Anidulafungin) is not recommended during pregnancy. Effective contraception should be used in women of childbearing age. Contact your doctor immediately if you become pregnant while taking Eraxis (Anidulafungin).

The effect of Eraxis (Anidulafungin) in breast-feeding women is not known. Ask your doctor for advice before taking Eraxis (Anidulafungin) while breast-feeding.

Eraxis (Anidulafungin) contains fructose

This medicine contains fructose (a type of sugar) in each vial. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you have hereditary fructose intolerance (HFI), a rare genetic disorder, you must not receive this medicine. Patients with HFI cannot break down fructose in this medicine, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you have HFI.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

3. How to take Eraxis (Anidulafungin)

Eraxis (Anidulafungin) will always be prepared and given to you by a doctor or a healthcare professional.

For Candidemia and other *Candida* infections (intra-abdominal abscess and peritonitis), the treatment starts with 200 mg on the first day (loading dose). This will be followed by a daily dose of 100 mg (maintenance dose).

For Esophageal Candidiasis, the treatment starts with 100 mg on the first day (loading dose). This will be followed by a daily dose of 50 mg (maintenance dose). You will be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms.

Your doctor will determine the duration of your treatment and how much Eraxis (Anidulafungin) you will receive each day and will monitor your response and condition.

In general, your treatment should continue for at least 14 days after the last day *Candida* was found in your blood.

If you receive more Eraxis (Anidulafungin) than you should
If you are concerned that you may have been given too much Eraxis (Anidulafungin), tell your doctor or another healthcare professional immediately.

If you forgot to use Eraxis (Anidulafungin)
As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However tell your doctor if you think that a dose has been forgotten.

You should not be given a double dose by doctor.

If you stop using Eraxis (Anidulafungin)
You should not experience any effects from Eraxis (Anidulafungin) if your doctor stops Eraxis (Anidulafungin) treatment.

If your original symptoms come back, tell your doctor or another healthcare professional immediately.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of these side effects will be noted by your doctor while monitoring your response and condition.

Life-threatening allergic reactions that might include difficulty breathing with wheezing or worsening of an existing rash have been rarely reported during administration of Eraxis (Anidulafungin).

Serious side effects – tell your doctor or another healthcare professional immediately should any of the following occur:

- Convulsion (seizure)
- Flushing
- Rash, pruritis (itching)
- Hot flush
- Hives
- Sudden contraction of the muscles around the airways resulting in wheezing or coughing
- Difficulty of breathing

Other side effects

Very common side effects (may affect more than 1 in 10 people) are:
- Low blood potassium (hypokalaemia)
- Diarrhoea
- Nausea

Common side effects (may affect up to 1 in 10 people) are:
- Convulsion (seizure)
- Headache
- Vomiting
- Changes in blood tests of liver function
- Rash, pruritis (itching)
- Changes in blood tests of kidney function
- Abnormal flow of bile from the gallbladder into the intestine (cholestasis)
- High blood sugar
- High blood pressure
- Low blood pressure
- Sudden contraction of the muscles around the airways resulting in wheezing or coughing
- Difficulty of breathing

Uncommon side effects (may affect up to 1 in 100 people) are:
- Disorder of blood clotting system
- Flushing
- Hot flush
- Stomach pain
- Hives
- Pain at injection site

Not known (frequency cannot be estimated from the available data) are:
- Life-threatening allergic reactions

5. How to store Eraxis (Anidulafungin)

Store in a refrigerator 2ºC – 8ºC (36ºF – 46ºF). Do not freeze.
Excursions for 96 hours up to 25°C (77ºF) are permitted, and the vial can be returned to storage at 2°C – 8°C (36°F – 46°F).
The reconstituted solution may be stored up to 25ºC for up to 24 hours.
The infusion solution may be stored at 25ºC (room temperature) for 48 hours (do not freeze).

6. Contents of the pack and other information

What Eraxis (Anidulafungin) contains

- The active substance is anidulafungin. Each vial of powder contains 100 mg anidulafungin.
- The other ingredients are: fructose (see section 2 “Eraxis (Anidulafungin) contains fructose”), mannitol, polysorbate 80, tartaric acid, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment) and water for injections.

What Eraxis (Anidulafungin) looks like and contents of the pack

100 mg lyophile in a 30 mL Type 1 glass vial with an elastomeric stopper (butyl rubber with an inert polymer coating on the product contact surface and lubricant on the top surface for easier machinability) and aluminum seal with flip-off cap.

Anidulafungin will be marketed as a box containing:
1 vial of 100 mg powder

Manufactured by:

M/s Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo-49001, Michigan, USA

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