

# ERAXIS®

## powder for injection

*anidulafungin*

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### Consumer Medicine Information

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#### What is in this leaflet

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This leaflet answers some common questions about ERAXIS.

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 taking ERAXIS against the benefits it is expected to 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.

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#### What ERAXIS is used for

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ERAXIS belongs to a group of medicines called echinocandins which work by preventing the growth of fungal organisms causing your infection.

ERAXIS is used to treat fungal infections such as invasive candidiasis and candidemia.

These are serious fungal infections in your bloodstream or in tissues or organs such as the food pipe or eyes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

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#### Before you are given ERAXIS

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##### *When you will not be given ERAXIS*

You will not be given ERAXIS if you have ever had an allergy to:

- any medicine containing anidulafungin
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as Candidas (not all brands given).

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives.

##### *Before you are given ERAXIS*

Tell your doctor if you have allergies to any foods, preservatives or dyes or any other medicines.

Tell your doctor if you have or have had any of the following medical conditions:

- any problems affecting your liver.

Your doctor may need to monitor the function of your liver using blood tests. Be sure to follow your doctor's advice if regular checks on your liver are recommended.

Tell your doctor if you are pregnant or plan to become pregnant.

ERAXIS should not be used during pregnancy. Effective contraception should be used in women of childbearing potential. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

ERAXIS should not be used whilst breastfeeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell your doctor before you are given ERAXIS.

##### *Taking other medicines*

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

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 such as

- tacrolimus, used to help prevent organ transplant rejection or to treat certain problems with the immune system
- rifampicin, an antibiotic used to treat tuberculosis and other infections
- cyclosporine, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system

- voriconazole, used to treat fungal infections
- liposomal amphotericin B, used to treat fungal infections or to prevent fungal infection following liver transplant.

However, do not start or stop any other medications without your doctor or pharmacist's approval.

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## How ERAXIS is given

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ERAXIS is given as a slow injection into a vein.

ERAXIS will only be given by a doctor or nurse.

Your doctor will decide how much ERAXIS you will be given each day.

Your doctor will decide for how long you will receive ERAXIS. This depends on your condition and other factors.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

### *In case of 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 pharmacist immediately.

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## Side effects

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

This medicine helps most people with fungal infections, 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. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following lists of possible side effects.

You may not experience any of them.

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

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

- blurred vision, eye pain
- nausea, feeling sick, vomiting
- headache
- flushing
- soreness at the injection site
- itching, rash, hives
- pain on swallowing
- difficulty breathing
- stomach pain, indigestion, diarrhoea, constipation
- changes in blood pressure
- aching muscles, joints or bones, back pain.

These side effects include the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- light headedness, fainting, seizures or fits, dizziness
- increased heart rate
- blood in urine
- uncontrollable bleeding, bruising
- fever, signs of frequent or worsening infections.

These may be signs of a serious allergic reaction or side effect. You may need urgent medical attention.

Other side effects not listed above may happen in some people. Some of these side effects can only be found when your doctor does tests to check your progress.

Tell your doctor if you notice any other side effects.

Other side effects not listed above may also occur in some people.

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## After using ERAXIS

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### *Effects when treatment with ERAXIS is stopped*

Your doctor may prescribe another medicine following your treatment with ERAXIS to prevent return of the fungal infection.

If your original symptoms come back, tell your doctor, nurse or pharmacist immediately.

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

### *Storage*

ERAXIS will be stored in the pharmacy or on the hospital ward and is kept at 2°C to 8°C (Do not freeze).

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## Product description

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### *What it looks like*

ERAXIS is supplied as a pack containing 1 vial of 100 mg anidulafungin. This is to be dissolved with water for injections prior to use in an infusion.

## *Ingredients*

### **Active Ingredients**

ERAXIS contains 100 mg of anidulafungin as the active ingredient in each vial.

### **Inactive Ingredients**

- fructose
- mannitol (E421)
- polysorbate 80 (E433)
- tartaric acid (E334)
- sodium hydroxide
- hydrochloric acid

## *Supplier*

ERAXIS is supplied in Australia by:

**Pfizer Australia Pty Ltd**

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll Free Number: 1800 675 229

Australian Registration Number

Aust R: 134398

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