

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is subject to additional monitoring due to approval of an extension of indications. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being treated with Eraxis?

Eraxis contains the active ingredient anidulafungin. It is used to treat serious fungal infections caused by yeast, such as candidiasis and candidaemia in adults and children one month and older. For more information, see Section 1. Why am I being treated with Eraxis? in the full CMI.

2. What should I know before treatment with Eraxis?

Do not start treatment if you/ your child have ever had an allergic reaction to any medicine containing anidulafungin, any of the ingredients listed at the end

of this CMI, or any other similar medicines such as Cancidas (not all brands given)

Tell the doctor if you/your child have had any allergic reaction to any antifungal, or any foods, preservatives or dyes or any other medicines, have liver problems, have intolerance to sugars such as fructose if you are pregnant, plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before treatment with Eraxis? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Eraxis and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Eraxis given?

Eraxis is given as a slow injection into the vein. The doctor will decide how much Eraxis will be given to you each day and for how long. It will depend on your condition and other factors. More instructions can be found in Section 4. How is Eraxis given? in the full CMI.

5. What should I know during treatment with Eraxis?

Things you should do	
	<ul style="list-style-type: none">• Tell the doctor if you/your child have liver problems, have

	<p>intolerance to sugars such as fructose if you are pregnant, plan to become pregnant or are breastfeeding</p> <ul style="list-style-type: none"> • For more information on "Things you should do" can be found in Section 6 in the full CMI
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not start treatment if you/ your child have ever had an allergic reaction to any medicine containing anidulafungin, any of the ingredients listed at the end of this CMI, or any other similar medicines such as Cancidas (not all brands given) • You should not breastfeed your infant while on treatment with Eraxis
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Eraxis should be stored in the pharmacy or on the hospital ward and is kept in a refrigerator at 2°C to 8°C. The reconstituted solution can be utilised for up to

	24 hours when stored at 25°C and the infusion solution can be utilised for up to 48 hours from preparation when stored at 25°C.
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For more information, see Section [5. What should I know while during treatment with Eraxis?](#) in the full CMI.

6. Are there any side effects?

Side effects may include low blood potassium (hypokalaemia), stomach pain, indigestion, diarrhoea, nausea, fainting, seizures or fits, dizziness, headache, vomiting, changes in liver function, rash, pruritis (itching), blood in urine, changes in blood pressure, increased heart rate, hot flushes, hives, asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, abnormal flow of bile from the gallbladder into the intestine (cholestasis), uncontrollable bleeding, bruising, aching muscles, joints or bones, back pain, blurred vision, eye pain, soreness at the injection site, signs of frequent or worsening infections.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

Eraxis[®]

anidulafungin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Eraxis. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Eraxis**

Where to find information in this leaflet:

- [1. Why am I being treated with Eraxis?](#)
- [2. What should I know before treatment with Eraxis?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Eraxis given ?](#)
- [5. What should I know during treatment with Eraxis?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with Eraxis?

Eraxis contains the active ingredient anidulafungin. 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 serious fungal infections caused by yeast, such as candidiasis and candidaemia, in adults and children one month and older.

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

2. What should I know before treatment with Eraxis?

Warnings

Do not use start treatment with Eraxis if you/ your child:

- are allergic to anidulafungin, or any of the ingredients listed at the end of this leaflet, or any other similar medicines such as Cancidas (not all brands given)
- Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you/your child:

- have any other medical conditions [liver problems]
- Your doctor may need to monitor the function of the liver using blood tests. Be sure to follow the doctor's advice if regular checks on your/ your child's liver are recommended.
- have allergies to any foods, preservatives or dyes or any other medicines
- are taking medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Eraxis contains fructose

- This medicine contains fructose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
- If you/your child have hereditary fructose intolerance (HFI), a rare genetic disorder, you/your child 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/your child have HFI or if your child can no longer have sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

3. What if I am taking other medicines?

Tell your doctor if you/your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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/your child 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

- ciclosporin, 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/ your child's doctor or pharmacist's approval.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Eraxis.

4. How is Eraxis given?

How much will be given

- 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.

How long will Eraxis need to be given?

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

Follow the instructions provided by your/your child's doctor carefully.

If too much Eraxis is given

Your/your child's doctor will monitor your/your child's response and condition to determine what ERAXIS treatment is needed. However, if you are concerned that you/your child may have been given too much ERAXIS you/your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with Eraxis?

Things you should do

If you are a woman of childbearing potential, you should use effective contraceptive methods to prevent pregnancy during treatment with Eraxis.

Call your doctor straight away if you:

- Become pregnant while receiving Eraxis

Remind any doctor, dentist, or pharmacist you visit that you are using Eraxis.

Things you should not do

- You should not breastfeed your infant while on treatment with Eraxis
- Do not start treatment if you/your child have hereditary fructose intolerance (HFI)
- Do not start treatment if you/ your child have ever had an allergic reaction to any medicine containing anidulafungin, any of the ingredients listed at the end of this CMI
- Do not start or stop any other medications without your/your child's doctor or pharmacist's approval

Driving or using machines

No information available

Drinking alcohol

No information available

Looking after your medicine

Eraxis should be stored in the pharmacy or on the hospital ward and should be kept in a refrigerator at 2°C to 8°C (Do not freeze).

The reconstituted solution can be utilised for up to 24 hours when stored at 25°C and the infusion solution can be utilised for up to 48 hours from preparation when stored at 25°C.

When to discard your medicine

Discard any medicine that has passed the expiry date.

This medicine should only be used on one patient on one occasion only.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● blurred vision, eye pain ● nausea, vomiting ● headache ● hot flushes ● soreness at the injection site ● itching, rash, hives ● pain on swallowing ● stomach pain, indigestion, diarrhoea, constipation ● changes in blood pressure ● aching muscles, joints or bones, back pain ● intense itching, dark urine and light-coloured bowel movements (cholestasis) ● low blood potassium which can result in fatigue, muscle cramps and abnormal heart rhythms (hypokalemia) * ● changes in liver function* ● changes in kidney function* 	<p>Speak to your doctor if you/your child have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
* These side effects may show up when you have a blood test.	

Serious side effects	What to do
<ul style="list-style-type: none"> ● swelling of the face, lips or tongue ● difficulty in swallowing or breathing ● asthma, wheezing, shortness of breath ● fainting, seizures or fits, dizziness ● increased heart rate ● blood in urine ● uncontrollable bleeding, bruising ● signs of frequent or worsening infections. <p>An additional side effect in low-birth weight infants may be nausea, vomiting, fast breathing and lethargy (metabolic acidosis)</p>	<p>Call your/your child's doctor immediately, or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you/your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Eraxis contains

Active ingredient	Anidulafungin
Other ingredients	fructose mannitol (E421)

	polysorbate 80 (E433) (250mg/vial) tartaric acid (E334) sodium hydroxide hydrochloric acid
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Do not take this medicine if you are allergic to any of these ingredients.

What Eraxis looks like

Eraxis is available as white to off-white lyophilised powder in a clear glass vial. This is to be dissolved with water for injections prior to use in an infusion.

ERAXIS is supplied as a pack containing 1 vial of 100 mg anidulafungin

Australian Registration Number (Aust R 134398).

Who distributes Eraxis

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in October 2021.