

Package leaflet: Information for the user

Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion

anidulafungin

Read all of this leaflet carefully before you or your child start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- If you or your child get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Anidulafungin is and what it is used for
2. What you need to know before you or your child are given Anidulafungin
3. How Anidulafungin is given
4. Possible side effects
5. How to store Anidulafungin
6. Contents of the pack and other information



1. What Anidulafungin is and what it is used for

This medicine contains the active substance anidulafungin and is prescribed in adults and in paediatric patients aged 1 month to less than 18 years 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*.

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

Anidulafungin prevents normal development of fungal cell walls. In the presence of Anidulafungin, fungal cells have incomplete or defective cell walls, making them fragile or unable to grow.

2. What you need to know before you or your child are given Anidulafungin

You must not be given Anidulafungin

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given 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,
- if you are given anaesthetics during your treatment with Anidulafungin;
- for signs of an infusion-related reaction which could include a rash, hives, itching, redness;
- for shortness of breath/breathing difficulties, dizziness or lightheadedness.

Children and adolescents

Anidulafungin should not be given to patients under 1 month of age.

Other medicines and Anidulafungin

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

The effect of Anidulafungin in pregnant women is not known. Therefore 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 this medicine.

The effect of Anidulafungin in breast-feeding women is not known.

Anidulafungin contains sodium and fructose

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium free'.

This medicine contains 100 mg fructose in each vial. If you or your child 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 or your child have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

3. How Anidulafungin is given

Anidulafungin will always be prepared and given to you or your child by a doctor or a healthcare professional (there is more information about the method of preparation at the end of the leaflet in the section for medical and healthcare professionals only).

For use in adults, 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 use in children and adolescents (age from 1 month to less than 18 years), the treatment starts with 3.0 mg/kg (not to exceed 200 mg) on the first day (loading dose). This will be followed by a daily dose of 1.5 mg/kg (not to exceed 100 mg) (maintenance dose). The dose that is given depends on the patient's weight.

Anidulafungin should be given to you once a day, by slow infusion (a drip) into your vein. For adults, this will take at least 1.5 hours for the maintenance dose and 3 hours for the loading dose. For children and adolescents, the infusion may take less time depending on the patient's weight.

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.

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 Anidulafungin than you should

If you are concerned that you may have been given too much Anidulafungin, tell your doctor or another healthcare professional immediately.

If you forget to use 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 or nurse if you think that a dose has been forgotten.

You should not be given a double dose to make up for the forgotten dose.

If you stop using Anidulafungin

You should not experience any effects from Anidulafungin if your doctor stops Anidulafungin treatment.

Your doctor may prescribe another medicine following your treatment with Anidulafungin to continue treating your fungal infection or prevent it from returning.

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, pharmacist or nurse.

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 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 in wheezing or coughing
- difficulty in breathing

The following information is intended for medical or healthcare professionals only and applies only to the single vial Anidulafungin Fresenius Kabi 100 mg powder for concentrate for solution for infusion presentation:

The contents of the vial must be reconstituted with water for injection and subsequently diluted with ONLY 9 mg/mL (0.9%) sodium chloride for infusion or 50 mg/mL (5%) glucose for infusion. The compatibility of reconstituted Anidulafungin with intravenous substances, additives, or medicines other than 9 mg/mL (0.9%) sodium chloride for infusion or 50 mg/mL (5%) glucose for infusion has not been established.

Reconstitution

Aseptically reconstitute each vial with 30 mL water for injections to provide a concentration of 3.33 mg/mL. The reconstitution time can be up to 2 minutes. After subsequent dilution, the solution is to be discarded if particulate matter or discoloration is identified. The appearance after reconstitution is a clear, colourless to light yellow solution.

The reconstituted solution may be stored up to 25°C for up to 24 hours prior to further dilution.



Dilution and infusion

Aseptically transfer the contents of the reconstituted vial(s) into an intravenous bag (or bottle) containing either 9 mg/mL (0.9%) sodium chloride for infusion or 50 mg/mL (5%) glucose for infusion obtaining an anidulafungin final infusion solution concentration of 0.77 mg/mL. For children and adolescents, the volume of infusion solution required to deliver the dose will vary depending on the patient's weight. The table below provides the volumes required for each dose.

Dilution requirements for Anidulafungin administration

Dose	100 mg	200 mg
Number of vials of powder	1	2
Total reconstituted volume	30 mL	60 mL
Infusion volume ^A	100 mL	200 mL
Total infusion volume ^B	130 mL	260 mL
Rate of infusion	1.4 mL/ min	1.4 mL/ min
Minimum duration of infusion	90 min	180 min

^A Either 9 mg/mL (0.9%) sodium chloride for infusion or 50 mg/mL (5%) glucose for infusion

^B Infusion solution concentration is 0.77 mg/mL



Other side effects

- Very common (may affect more than 1 in 10 people):
- low blood potassium (hypokalaemia)
- diarrhoea
- nausea

Common (may affect up to 1 in 10 people):

- 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 in breathing

Uncommon (may affect up to 1 in 100 people):

- 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):

- life-threatening allergic reactions

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For UK - The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For Ireland - HPA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Andialufungin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.



Store in a refrigerator (2°C - 8°C).

The reconstituted solution may be stored up to 25°C for up to 24 hours. The infusion solution may be stored at 25°C for 48 hours. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw

away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Andialufungin contains**

- The active substance is andialufungin. Each vial of powder contains 100 mg andialufungin.
- The other ingredients are: fructose, mannitol, polysorbate 80, tartaric acid, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment).

What Andialufungin looks like and contents of the pack

Andialufungin is supplied as a box containing 1 vial of 100 mg powder for concentrate for solution for infusion.

The powder is white to off-white.

Marketing Authorisation Holder**For UK**

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Manor Park, Runcorn, Cheshire

WA7 1NT, UK

For IE

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Eise-Kroener-Strasse 1
61352 Bad Homburg v.d.H
Germany

Manufacturer:

Laboratori FUNDACIO DAU
C/ De la letra C, 12-14
Poligono Industrial de la Zona Franca

08040 Barcelona, Spain



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The rate of infusion should not exceed 1.1 mg/min (equivalent to 1.4 mL/min when reconstituted and diluted per instructions). Parenteral medicinal products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either particulate matter or discoloration are identified, discard the solution.

For single use only. Waste materials should be disposed of in accordance with local requirements.

