Package leaflet: Information for the user

Anidulafungin 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 use Anidulafungin
3. How to use Anidulafungin
4. Possible side effects
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1. What Anidulafungin is and what it is used for

Anidulafungin 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 use Anidulafungin

Do not use 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 or pharmacist or nurse before using Anidulafungin.

Your doctor may decide to monitor
- your liver function more closely if you develop liver problems during your treatment.
- if you are given anaesthetics during your treatment with Anidulafungin, 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.

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
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 Anidulafungin.
The effect of Anidulafungin in breast-feeding women is not known. Ask your doctor or pharmacist for advice before taking Anidulafungin while breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicines.

Anidulafungin contains fructose and sodium
This medicine contains 100 mg fructose in each vial.

If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or 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 (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.
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to use Anidulafungin

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 forgot 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 pharmacist if you think that a dose has been forgotten.

You should not be given a double dose by your doctor.

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, or 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, pruritus (itching)
- Hot flush
- Hives
- Sudden contraction of the muscles around the airways resulting in wheezing or coughing
- Difficulty 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, pruritus (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 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA 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 Anidulafungin

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 and the carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Chemical and physical in-use stability of the reconstituted concentrate for solution for infusion has been demonstrated for 24 hours at 25ºC.

The infusion solution may be stored at 25°C (room temperature) for 48 hours (do not freeze) and should be administered at 25°C (room temperature) within 48 hours.
From a microbiological point of view the product should be used immediately. If not used immediately, the in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

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 Anidulafungin contains
- The active substance is anidulafungin. Each vial of powder contains 100 mg anidulafungin. The reconstituted concentrate for solution for infusion contains 3.33 mg/ml anidulafungin and the diluted solution for infusion contains 0.77 mg/ml anidulafungin.
- The other ingredients are: fructose, mannitol, polysorbate 80, lactic acid, sodium hydroxide (for pH-adjustment), hydrochloric acid, concentrated (for pH-adjustment)

What Anidulafungin looks like and contents of the pack
Anidulafungin is white to off-white cake or powder.

Anidulafungin is supplied as a box containing 1 vial with powder for concentrate for solution for infusion.

Pack size: 1 vial.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Pharmidea SIA, Rūpnīcu iela 4, Olaine, Olaines novads, LV-2114, Latvia.
Lyocontract GmbH, Pulverwiese 1, Ilsenburg 38871, Germany.
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Anidulafungin Sandoz 100 mg - Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Belgium	Anidulafungin Sandoz 100 mg poeder voor concentraat voor oplossing voor infusie
Croatia	Anidulafungin Sandoz 100 mg prašak za koncentrat za otopinu za infuziju
Czech Republic	Anidulafungin Sandoz

Denmark	Anidulafungin Sandoz
Estonia	Anidulafungin Sandoz
Germany	Anidulafungin HEXAL 100 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Ireland	Anidulafungin 100 mg Powder for concentrate for solution for infusion
Italy	Anidulafungina Sandoz
Latvia	Anidulafungin Sandoz 100 mg pulveris infūziju šķīduma koncentrāta pagatavošanai
Poland	Anidulafungin Sandoz
Romania	Anidulafungină Sandoz 100 mg pulbere pentru concentrat pentru soluţie perfuzabilă
Slovak Republic	Anidulafungin Sandoz 100 mg
Slovenia	Anidulafungin Sandoz 100 mg prašek za koncentrat za raztopino za infundiranje
Sweden	Anidulafungin Sandoz, 100 mg pulver till koncentrat till infusionsvätska, lösning
The Netherlands	Anidulafungine Sandoz 100 mg, poeder voor concentraat voor oplossing voor infusie

This leaflet was last revised in 09/2020.

The following information is intended for medical or healthcare professionals only and applies only to the single vial Anidulafungin 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 5 minutes. Reconstituted solution is clear, colourless and practically free of visible particles. After subsequent dilution, the solution is to be discarded if particulate matter or discoloration is identified.

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	Number of vials of powder	Total reconstituted volume	Volume of infusion diluent[A]	Total infusion volume[B]	Rate of infusion	Minimum duration of infusion
100 mg	1	30 ml	100 ml	130 ml	1.4 ml/min	90 min
200 mg	2	60 ml	200 ml	260 ml	1.4 ml/min	180 min

[A] Either 9 mg/ml (0.9%) sodium chloride for infusion or 50 mg/ml (5%) glucose for infusion.
[B] Solution for infusion concentration is 0.77 mg/ml.

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 discolouration are identified, discard the solution.

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