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 nurse.
- If you or your child get any side effects, talk to your doctor 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

Anidulafungin contains the active substance anidulafungin. Anidulafungin belongs to a group of medicines called echinocandins, which are used to treat serious fungal infections.

This medicine is used in adults and children 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 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, pharmacist or nurse before using anidulafungin. Your doctor may decide to monitor you:
- for liver function more closely if you develop liver problems during your treatment.
- if you are given anaesthetics during your treatment with anidulafungin 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

Children and adolescents
Anidulafungin should not be given to children 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
Anidulafungin is not recommended during pregnancy, since the effect of anidulafungin in pregnant women is not known. 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.

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

Anidulafungin contains fructose
This medicine contains 102.5 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.

Anidulafungin contains sodium
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 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, 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:

Common side effects (may affect up to 1 in 10 people):
- Convulsion (seizure)
- Sudden contraction of the muscles around the airways resulting in wheezing or coughing
- Difficulty of breathing

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

Other side effects

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

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

Uncommon side effects (may affect up to 1 in 100 people):
- Disorder of blood clotting system
- Flushing

- Hot flush
- Stomach pain
- Hives
- Pain at injection site

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
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 carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C).

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

Solution for infusion
The infusion solution may be stored at 25 ºC for 48 hours. Chemical and physical in-use stability of the solution for infusion has been demonstrated for 48 hours at 25 ºC and for 72 hours frozen.

From a microbiological point of view, once reconstituted or diluted, the product must be used immediately. If not used immediately, 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 °C to 8 °C (in a refrigerator), unless reconstitution and dilution have 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. Content of the pack and other information

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

What Anidulafungin looks like and contents of the pack
Anidulafungin 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
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer(s)
Laboratori FUNDACIO DAU, C/ De la letra C 12-14,
Poligono Industrial de la Zona Franca, Barcelona, Spain

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

Austria	Anidulafungin Mylan 100 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Belgium	Anidulafungin Mylan 100 mg, poeder voor concentraat voor oplossing voor infusie
Czech Republic	Anidulafungin Mylan
Denmark	Anidulafungin Mylan
Germany	Anidulafungin Mylan 100 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Finland	Anidulafungin Mylan 100 mg kuiva-aine välikonsentraatiksi infuusionestettä varten, liuos
Ireland	Anidulafungin 100 mg powder for concentrate for solution for infusion
Italy	Anidulafungina Mylan Pharma
Norway	Anidulafungin Mylan
Poland	Anidulafungin Mylan
Portugal	Anidulafungina Mylan
Romania	Anidulafungină Mylan 100 mg pulbere pentru concentrat pentru soluție perfuzabilă
Spain	Anidulafungina Mylan 100 mg polvo para concentrado para solución para perfusión EFG
Sweden	Anidulafungin Mylan
Slovakia	Anidulafungin Mylan 100 mg
United Kingdom	Anidulafungin 100mg powder for concentrate for solution for infusion

This leaflet was last approved in 03/2021

Other sources of information
Detailed information on this medicine is available on the web site of : {name of MS/Agency}

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The following information is intended for 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 sodium chloride 9 mg/mL (0.9 %) solution for infusion or 50 mg/mL (5 %) glucose for infusion. The compatibility of reconstituted Anidulafungin with intravenous substances, additives, or medicines other than sodium chloride 9 mg/mL (0.9 %) solution for infusion or 50 mg/mL (5 %) glucose for infusion has not been established.

Reconstitution
Aseptically reconstitute each vial with 30 mL water for injection to provide a concentration of

3.33 mg/mL. The reconstitution time can be up to 2 minutes. The appearance after reconstitution is a clear, colourless to light yellow solution.. 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.

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 sodium chloride 9 mg/mL (0.9 %) solution 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**	**Infusion volume [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 sodium chloride 9 mg/mL (0.9 %) solution for infusion or 50 mg/mL (5 %) glucose for infusion
[B] Infusion solution 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).

For single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.