

## **Package leaflet: Information for the user**

### **Anidulafungin 100 mg Powder for Concentrate for Solution for Infusion**

**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, pharmacist or nurse.
- If you or your child get any side effects, talk to your doctor, 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**
- 5. How to store Anidulafungin**
- 6. Contents of the pack and other information**

#### **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, micafungin), 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 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 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.

### **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, pruritus (itching)
- hot flush
- hives
- sudden contraction of the muscles around the airways resulting in wheezing or coughing
- difficulty of 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 of 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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. The expiry data 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 (room temperature) 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 Anidulafungin contains**

- The active substance is anidulafungin. Each vial of powder contains 100 mg anidulafungin.
- The other ingredients are: sucrose, polysorbate 80 (E 433), tartaric acid, sodium hydroxide (E 524) (for pH adjustment), hydrochloric acid (E 507) (for pH adjustment).

### **What Anidulafungin looks like and contents of the pack**

Anidulafungin is available as a powder for concentrate for solution for infusion in a box containing 1 vial.

The powder is white to off white powder, free of visible evidence of contamination.

### **Marketing Authorisation Holder**

TEVA UK Limited, Eastbourne, BN22 9AG, United Kingdom

### **Manufacturer**

Teva Operations Poland Sp. z o.o, ul. Mogilska 80, Krakow, 31-546, Poland

OR\*

Actavis Italy S.p.A, Viale Pasteur 10, Nerviano, Milan, 20014, Italy

OR\*

S.C. SINDAN-PHARMA S.R.L., 11th Ion Mihalache Boulevard, Bucharest, 011171, Romania

OR\*

Teva Pharma B.V., Swensweg 5, Haarlem, 2031GA, Netherlands

OR\*

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.), Prilaz baruna Filipovića 25, Zagreb, 10000, Croatia

**This leaflet was last revised in 12/2020.**

PL 00289/2142

*\*Only the actual site of batch release will appear on the printed version of the leaflet.*

<-----  
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 injections 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. The infusion solution must not be frozen.

### 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. After subsequent dilution, the solution is to be discarded if particulate matter or discolouration is identified. The appearance after reconstitution is a clear, colourless to 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) by adding slowly the solution 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, with constant gentle agitation, 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 <sup>A</sup>	Total infusion volume <sup>B</sup>	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

<sup>A</sup> 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.

The rate of infusion should not exceed 1.1 mg/min (equivalent to 1.4 mL/min when reconstituted and diluted per instructions).

The solution should be inspected visually for particulate matter and discolouration prior to administration. 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.