Package leaflet: Information for the user

Anidulafungin Teva 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, 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 Teva is and what it is used for

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

Anidulafungin Teva prevents normal development of fungal cell walls. In the presence of Anidulafungin Teva, 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 Teva

Do not use Anidulafungin Teva
- 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 Teva.

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

Other medicines and Anidulafungin Teva

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 Teva in pregnant women is not known. Therefore Anidulafungin Teva 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 Teva.

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

Ask your doctor or pharmacist for advice before taking any medicines.

Anidulafungin Teva 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 Teva

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

If you forgot to use Anidulafungin Teva
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 Teva
You should not experience any effects from Anidulafungin Teva if your doctor stops Anidulafungin Teva treatment.

Your doctor may prescribe another medicine following your treatment with Anidulafungin Teva 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 Teva.

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 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 Teva

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^{o} C – 8^{o}C).

The reconstituted solution may be stored up to 25^{o}C for up to 24 hours. 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.

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 Teva 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 Teva looks like and contents of the pack

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

Manufacturer
Teva Operations Poland Sp. z.o.o, ul. Mogilska 80, Kraków, 31-546, Poland.
Actavis Italy S.p.A, Viale Pasteur 10, Nerviano, Milan, 20014, Italy.

S.C. SINDAN-PHARMA S.R.L., 11th Ion Mihalache Boulevard, Bucharest, 011171, Romania.
Teva Pharma B.V., Swensweg 5, Haarlem, 2031GA, Netherlands.
PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.), Prilaz baruna Filipovića 25, Zagreb, 10000, Croatia.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Anidulafungin ratiopharm 100 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Belgium	Anidulafungin Teva 100 mg poeder voor concentraat voor oplossing voor infusie/poudre pour solution à diluer pour perfusion/ Pulver zur Herstellung eines Konzentrats für eine Infusionslösung
Croatia	Anidulafungin Pliva 100 mg prašak za koncentrat za otopinu za infuziju
Czech Republic	Anidulafungin Teva
Denmark	Anidulafungin Teva
Germany	Anidulafungin-ratiopharm 100 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Greece	Anidulafungin/Teva 100 mg κόνις για πυκνό σκεύασμα για παρασκευή διαλύματος προς έγχυση
Hungary	Anidulafungin-Teva 100 mg por oldatos infúzióhoz való koncentrátumhoz
Ireland	Anidulafungin Teva 100 mg Powder for Concentrate for Solution for Infusion
Italy	Anidulafungina Teva
Luxembourg	Anidulafungin Teva 100 mg poudre pour solution à diluer pour perfusion
Netherlands	Anidulafungine Teva 100 mg, poeder voor concentraat voor oplossing voor intraveneuze infusie
Poland	Anidulafungin Teva
Portugal	Anidulafungina Teva
Romania	Anidulafungină Teva 100 mg pulbere pentru concentrat pentru solutie perfuzabila
Spain	Anidulafungina Teva 100 mg polvo para concentrado para solución para perfusión EFG
Slovenia	Anidulafungin Teva 100 mg prašek za koncentrat za raztopino za infundiranje
Sweden	Anidulafungin Teva
United Kingdom	Anidulafungin 100mg Powder for concentrate for solution for infusion

This leaflet was last revised in September 2021.

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The following information is intended for medical or healthcare professionals only and applies only to the single vial Anidulafungin Teva 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 sodium chloride 9 mg/mL (0.9%) solution for infusion or 50 mg/mL (5%) glucose for infusion. The compatibility of reconstituted Anidulafungin Teva 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
Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. If either particulate matter or discolouration is identified, discard the solution.

Adult Patients
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, to obtain the appropriate anidulafungin concentration. The table below provides the dilution to a concentration of 0.77 mg/mL for the final infusion solution and infusion instructions for each dose.

Dilution requirements for Anidulafungin Teva 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 or 84 mL/ hour	90 min
200 mg	2	60 mL	200 mL	260 mL	1.4 mL/ Min or 84 mL/ hour	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

The rate of infusion should not exceed 1.1 mg/min (equivalent to 1.4 mL/min or 84 mL/ hour when reconstituted and diluted per instructions).

Paediatric Patients

For paediatric patients aged 1 month to < 18 years, the volume of infusion solution required to deliver the dose will vary depending on the weight of the patient. The reconstituted solution must be further diluted to a concentration of 0.77 mg/mL for the final infusion solution. A programmable syringe orinfusion pump is recommended. **The rate of infusion should not exceed 1.1 mg/minute (equivalentto 1.4 mL/minute or 84 mL/hour when reconstituted and diluted per instructions)** (see sections4.2 and 4.4).

1. Calculate patient dose and reconstitute vial(s) required according to reconstitution instructions to provide a concentration of 3.33 mg/mL

2. Calculate the volume (mL) of reconstituted anidulafungin required:

    - Volume of anidulafungin (mL) = Dose of anidulafungin (mg) ÷ 3.33 mg/mL

3. Calculate the total volume of dosing solution (mL) required to provide a final concentration of 0.77 mg/mL:

    - Total volume of dosing solution (mL) = Dose of anidulafungin (mg) ÷ 0.77 mg/mL

4. Calculate the volume of diluent [sodium chloride 9 mg/mL (0.9%) solution for infusion or 50 mg/mL (5%) glucose for infusion] required to prepare the dosing solution:

    - Volume of diluent (mL) = Total volume of dosing solution (mL) – Volume of anidulafungin (mL)

5. Aseptically transfer the required volumes (mL) of anidulafungin and sodium chloride 9 mg/mL (0.9%) solution for infusion or 50 mg/mL (5%) glucose for infusion into an infusion syringe or IV infusion bag needed for administration.

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