Package leaflet: Information for the user

ECALTA 100 mg powder for concentrate for solution for infusion
Anidulafungin

Read all of this leaflet carefully before you 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 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 ECALTA is and what it is used for

ECALTA contains the active substance anidulafungin and is prescribed in adults 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*.

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

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

2. What you need to know before you use ECALTA

Do not use ECALTA

- 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 ECALTA.

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 ECALTA.
- 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
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Children and adolescents

ECALTA should not be given to patients under 18 years of age.

Other medicines and ECALTA

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

Pregnancy and breast-feeding

The effect of ECALTA in pregnant women is not known. Therefore ECALTA 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 ECALTA.

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

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

ECALTA contains fructose
This medicine contains fructose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use ECALTA

ECALTA will always be prepared and given to you 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).

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).

ECALTA should be given to you once a day, by slow infusion (a drip) into your vein. This will take at least 1.5 hours for the maintenance dose and 3 hours for the loading dose.

Your doctor will determine the duration of your treatment and how much ECALTA 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 ECALTA than you should

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

If you forgot to use ECALTA
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 doctor.

If you stop using ECALTA

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

Your doctor may prescribe another medicine following your treatment with ECALTA 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 ECALTA.

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 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, 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 of breathing
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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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

5. How to store ECALTA

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 or stored frozen for at least 72 hours, and should be administered at 25°C (room temperature) within 48 hours.

Do not throw away any medicines via wastewater or household waste.

6. Contents of the pack and other information

What ECALTA contains

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

What ECALTA looks like and contents of the pack

ECALTA 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

Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium
Manufacturer

Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for medical or healthcare professionals only and applies only to the single vial ECALTA 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 ECALTA 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. 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^{o}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 concentration of 0.77 mg/mL. The table below provides the volumes required for each dose.

Dilution requirements for ECALTA 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 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).

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.

Ref: ECW 13_0