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Ecalta *(anidulafungin)*

An overview of Ecalta and why it is authorised in the EU

What is Ecalta and what is it used for?

Ecalta is used to treat patients from one month of age with invasive candidiasis (a fungal infection caused by a yeast called *Candida*). 'Invasive' means that the fungus has spread into the bloodstream.

Ecalta contains the active substance anidulafungin.

How is Ecalta used?

Ecalta can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of invasive fungal infections.

Ecalta is available for infusion (drip) into a vein. In adults, Ecalta is given as an initial dose of 200 mg on day one, followed by 100 mg each day from day two. In children, the dose depends on body weight: the initial dose is 3 mg per kg bodyweight on day 1, followed by half this dose from day two. The duration of treatment depends on how the patient responds. In general, treatment should continue for at least two weeks after the last day that fungus is found in the patient's blood.

For more information about using Ecalta, see the package leaflet or contact your doctor or pharmacist.

How does Ecalta work?

The active substance in Ecalta, anidulafungin, is an antifungal medicine, which belongs to the group 'echinocandins'. It works by interfering with the production of a component of the fungal cell wall called 1,3 β D glucan. Fungal cells treated with Ecalta have incomplete or defective cell walls, making them fragile and unable to grow. The list of fungi against which Ecalta is active can be found in the summary of product characteristics (also part of the EPAR).

What benefits of Ecalta have been shown in studies?

Ecalta has been studied in one main study involving 261 patients aged between 16 and 91 years of age with invasive candidiasis and who did not have neutropenia (low white blood cell counts). Ecalta was

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compared with fluconazole (another antifungal medicine). Both medicines were given by infusion for between 14 and 42 days.

At the end of the treatment course, 76% of the patients (96 out of 127) receiving Ecalta responded to treatment and had a significant or complete improvement of symptoms, with no need for further antifungal treatment and no *Candida* found in the specimens taken from the patient. This compared with 60% (71 out of 118) of the patients receiving fluconazole.

In addition, an analysis of other studies evaluated the effects Ecalta in 46 adult patients with neutropenia and found that around 57% of patients (26 out of 46) had responded to treatment.

Ecalta was also studied in one main study involving 70 children aged between 1 month and 18 years with invasive candidiasis. Treatment with Ecalta for 10 to 35 days led to a response in 70% (45 out of 64) of patients.

What are the risks associated with Ecalta?

The most common side effects with Ecalta (seen in more than 1 patient in 10) are diarrhoea, nausea (feeling sick) and hypokalaemia (low blood potassium levels). For the full list of side effects of Ecalta, see the package leaflet.

Ecalta must not be used in people who are hypersensitive (allergic) to anidulafungin or any of the other ingredients, or to any other medicines in the echinocandin class.

Why is Ecalta authorised in the EU?

The European Medicines Agency decided that Ecalta's benefits are greater than its risks for the treatment of invasive candidiasis in adults and children and it can be authorised for use in the EU. However, the Agency noted that Ecalta has been studied mainly in patients with candidaemia (*Candida* in the blood), and only in a limited number of patients with neutropenia (low white blood cell counts) or deep tissue infections or abscesses.

What measures are being taken to ensure the safe and effective use of Ecalta?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ecalta have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ecalta are continuously monitored. Side effects reported with Ecalta are carefully evaluated and any necessary action taken to protect patients.

Other information about Ecalta

Ecalta received a marketing authorisation valid throughout the EU on 20 September 2007.

Further information on Ecalta can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ecalta. This summary was last updated in 05-2020.