EMA/477972/2014
EMEA/H/C/000788

**EPAR summary for the public**

# Ecalta

anidulafungin

This is a summary of the European public assessment report (EPAR) for Ecalta. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ecalta.

For practical information about using Ecalta, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Ecalta?

Ecalta is a powder that is made up into a solution for infusion (drip) into a vein. Ecalta is available with or without a solvent. It contains the active substance anidulafungin.

## What is Ecalta used for?

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

The medicine can only be obtained with a prescription.

## How is Ecalta used?

Treatment with Ecalta should be started by a doctor who has experience in the management of invasive fungal infections.

Ecalta is given as an initial dose of 200 mg on day one, followed by 100 mg each day from day two. Ecalta should only be given by infusion, at a maximum rate of 1.1 mg per minute to avoid side effects: this corresponds to about three hours for the initial infusion, and one and a half hours for the subsequent infusions. The duration of treatment depends on how the patient responds. In general,

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

treatment should continue for at least two weeks after the last day that fungus is found in the patient's blood.

## 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, which is necessary for the fungus to continue living and growing. 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).

## How has Ecalta been studied?

Ecalta has been studied in one main study involving 261 patients with invasive candidiasis and who did not have neutropenia (low white blood cell counts). Ecalta was compared with fluconazole (another antifungal medicine). Both medicines were given by infusion, for between 14 and 42 days. An analysis of other studies evaluated the effects Ecalta in 46 patients with neutropenia. The main measure of effectiveness was the number of patients who had responded to treatment at the end of the treatment course. A response was defined as 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.

## What benefit has Ecalta shown during the studies?

Ecalta was more effective than fluconazole in treating invasive candidiasis in non-neutropenic patients. At the end of the treatment course, 76% of the patients receiving Ecalta had responded to treatment (96 out of 127), compared with 60% of the patients receiving fluconazole (71 out of 118). In the analysis of patients with neutropenia, around 57% of patients (26 out of 46) had responded to treatment.

## What is the risk 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 all side effects reported with 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 has Ecalta been approved?

The Committee for Medicinal Products for Human Use (CHMP) concluded that Ecalta's benefits are greater than its risks for the treatment of invasive candidiasis in adult patients. However, the Committee 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. The Committee recommended that Ecalta be given marketing authorisation.

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

A risk management plan has been developed to ensure that Ecalta is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ecalta, including the appropriate precautions to be followed by healthcare professionals and patients.

## Other information about Ecalta

The European Commission granted a marketing authorisation valid throughout the European Union for Ecalta on 20 September 2007.

The full EPAR for Ecalta can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ecalta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.