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EPAR summary for the public

Mycamine

micafungin

This is a summary of the European public assessment report (EPAR) for Mycamine. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Mycamine.

What is Mycamine?

Mycamine is a powder that is dissolved to make a solution for infusion (drip into a vein). It contains the active substance micafungin.

What is Mycamine used for?

Mycamine is used in babies, children and adults in the following situations:

- to treat invasive candidiasis (a type of fungal infection caused by a yeast-like fungus called *Candida*). 'Invasive' means that the fungus has spread into tissue and blood vessels;
- to prevent infection with *Candida* in patients who are having a bone marrow transplant or who are expected to have neutropenia (low levels of neutrophils, a type of white blood cell) for 10 days or more.

Mycamine is also used to treat candidiasis in the oesophagus (gullet) in patients over 16 years of age for whom intravenous treatment is suitable.

Because of a possible risk of liver tumours, Mycamine is only to be used if other antifungal medicines are not appropriate.

The medicine can only be obtained with a prescription.

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How is Mycamine used?

Treatment with Mycamine should be initiated by a doctor who has experience managing fungal infections, and after considering official or national guidance on the use of antifungal medicines.

Mycamine is given once a day as an infusion lasting around one hour. The dose depends on what it is being used for, the patient's weight, and the response to treatment.

Patients being treated for invasive candidiasis should receive Mycamine for at least two weeks, and for a week after symptoms have resolved and there are no signs of fungus in the blood.

Patients being treated for oesophageal candidiasis should continue to receive Mycamine for at least one week after symptoms have resolved.

When Mycamine is used to prevent *Candida* infection, treatment should continue for one week after white blood cell counts have recovered.

How does Mycamine work?

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

How has Mycamine been studied?

The effectiveness of Mycamine has been studied in four main studies, in which it was compared with other antifungal medicines. There were three treatment studies and one prevention study.

For the treatment of invasive candidiasis, Mycamine was compared with amphotericin B in a study involving 531 adults and 106 children, including newborns and premature babies.

For the treatment of oesophageal candidiasis, Mycamine was compared with fluconazole in a study involving 518 adults, and with caspofungin in another study involving 452 adults. Most of the patients in these two studies were infected with human immunodeficiency virus (HIV). In all three studies, the main measure of effectiveness was the number of patients in whom treatment was successful, based on an improvement in symptoms and eradication of the fungus at the end of treatment.

For the prevention of candidiasis, Mycamine was compared with fluconazole in 889 adults and children undergoing a bone marrow transplant. The main measure of effectiveness was the number of patients who did not develop a fungal infection during treatment or the following four weeks.

What benefit has Mycamine shown during the studies?

Mycamine was as effective as the comparator medicines in the treatment of candidiasis. In the study of invasive candidiasis, around 90% of the adults receiving either Mycamine or amphotericin B were successfully treated. Similar results were seen in children.

In the two studies of oesophageal candidiasis, around 90% of the patients were successfully treated with Mycamine, fluconazole or caspofungin.

Mycamine was more effective than fluconazole in preventing fungal infection in patients undergoing a bone marrow transplant: 80% of the patients (340 out of 425) receiving Mycamine did not develop a fungal infection, compared with 74% of the patients (336 out of 457) receiving fluconazole.

What is the risk associated with Mycamine?

The most common side effects with Mycamine (seen in between 1 and 10 patients in 100) are leucopenia (low levels of leucocytes, a type of white blood cell), neutropenia (low levels of neutrophils, a type of white blood cell), anaemia (low red blood cell counts), hypokalaemia (low blood potassium levels), hypomagnesaemia (low blood magnesium levels), hypocalcaemia (low blood calcium levels), headache, phlebitis (inflammation of a vein), nausea (feeling sick), vomiting, diarrhoea, abdominal (tummy) pain, signs of liver problems in the blood (increased levels of alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase or bilirubin), rash, pyrexia (fever) and rigors (shaking chills).

Additional common side effects in children (seen in between 1 and 10 children in 100) are thrombocytopenia (low blood platelet counts), tachycardia (rapid heart rate), hypertension (high blood pressure), hypotension (low blood pressure), hepatomegaly (enlarged liver), acute renal failure (sudden kidney failure) and increased blood urea levels.

For the full list of all side effects reported with Mycamine, see the package leaflet.

Mycamine should not be used in people who may be hypersensitive (allergic) to micafungin, other echinocandins, or any of the other ingredients.

Because liver damage and tumours have been seen in rats receiving Mycamine for long periods, patients should be monitored for liver problems during Mycamine treatment using blood tests. Treatment should be stopped if there are persistent increases in liver enzymes. Mycamine should only be used after careful assessment of its risks and benefits, particularly in patients who have existing liver problems. Mycamine is not recommended for use in patients who have severe problems with their liver, who have long-term liver disease or who are taking other medicines that could harm the liver or the DNA.

Why has Mycamine been approved?

The CHMP decided that Mycamine's benefits are greater than its risks for the treatment of invasive candidiasis and of oesophageal candidiasis, and for the prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or who are expected to have neutropenia for 10 or more days. However due to a possible risk of liver tumour, based on results seen in rats, the Committee recommended that Mycamine should only be used if other antifungal medicines are not appropriate.

What measures are being taken to ensure the safe use of Mycamine?

The company that makes Mycamine will ensure that prescribers in all Member States receive a checklist before the launch of the medicine. This checklist will remind prescribers how to use the medicine safely.

Other information about Mycamine

The European Commission granted a marketing authorisation valid throughout the European Union for Mycamine on 25 April 2008.

The full EPAR for Mycamine 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 Mycamine, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2011.