

Summary Public Assessment Report

Micafungin Reig Jofre (micafungin sodium dihydrate)

SE/H/2049/01-02/DC

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Micafungin Reig Jofre
micafungin sodium dihydrate

Powder for concentrate for solution for infusion, 50 mg, 100 mg

This is a summary of the public assessment report (PAR) for Micafungin Reig Jofre. It explains how Micafungin Reig Jofre was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Micafungin Reig Jofre.

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

What is Micafungin Reig Jofre and what is it used for?

Micafungin Reig Jofre is a 'generic medicine'. This means that Micafungin Reig Jofre is similar to a 'reference medicine' already authorised in the European Union (EU) called Mycamine.

Micafungin Reig Jofre is called an antifungal medicine because it is used to treat infections caused by fungal cells. Micafungin Reig Jofre is used to treat fungal infections caused by fungal or yeast cells called Candida. Micafungin Reig Jofre is effective in treating systemic infections (those that have penetrated within the body).

How does Micafungin Reig Jofre work?

Micafungin Reig Jofre contains the active substance micafungin, which is an antifungal medicine. It interferes with the production of an essential component of the fungal cell wall. An intact cell wall is necessary for the fungus to continue living and growing. Micafungin Reig Jofre causes defects in the fungal cell wall, making the fungus unable to live and grow.

How is Micafungin Reig Jofre used?

The pharmaceutical form of Micafungin Reig Jofre is powder for concentrate for solution for infusion for intravenous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Micafungin Reig Jofre have been shown in studies?

No additional studies were needed as Micafungin Reig Jofre is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Mycamine.

What are the possible side effects of Micafungin Reig Jofre?

Because Micafungin Reig Jofre is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Micafungin Reig Jofre approved?

It was concluded that, in accordance with EU requirements, Micafungin Reig Jofre has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Mycamine. Therefore, the Medical Products Agency in Sweden decided that, as for Mycamine, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Micafungin Reig Jofre?

A risk management plan has been developed to ensure that Micafungin Reig Jofre 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 Micafungin Reig Jofre, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Micafungin Reig Jofre

The full PAR for Micafungin Reig Jofre can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Micafungin Reig Jofre, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-01.