LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Anidulafungin Reig Jofre (anidulafungin)

SE/H/1960/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Anidulafungin Reig Jofre
anidulafungin

Powder for concentrate for solution for infusion, 100 mg

This is a summary of the public assessment report (PAR) for Anidulafungin Reig Jofre. It explains how Anidulafungin 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 Anidulafungin Reig Jofre.

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

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

Anidulafungin Reig Jofre is a 'generic medicine'. This means that Anidulafungin Reig Jofre is similar to a 'reference medicine' already authorised in the European Union (EU) called ECALTA.
Anidulafungin Reig Jofre is used in the treatment of fungal infection of the blood or other internal organs called invasive candidiasis. The infection is caused by fungal cells (yeasts) called Candida.

How does Anidulafungin Reig Jofre work?

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

How is Anidulafungin Reig Jofre used?

The pharmaceutical form of Anidulafungin Reig Jofre is powder for concentrate for solution for infusion (administered by a healthcare professional slowly into a vein).

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 Anidulafungin Reig Jofre have been shown in studies?

No additional studies were needed as Anidulafungin Reig Jofre is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, ECALTA.

What are the possible side effects of Anidulafungin Reig Jofre?

Because Anidulafungin 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 Anidulafungin Reig Jofre approved?

It was concluded that, in accordance with EU requirements, Anidulafungin Reig Jofre has been shown to have comparable quality and to be similar to the reference medicine ECALTA. Therefore, the Medical Products Agency in Sweden decided that, as for ECALTA, 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 Anidulafungin Reig Jofre?

A risk management plan has been developed to ensure that Anidulafungin 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 Anidulafungin 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 Anidulafungin Reig Jofre

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

This summary was last updated in 2020-05.