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Rezzayo (*rezafungin*)

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

What is Rezzayo and what is it used for?

Rezzayo is an antifungal medicine used to treat adults with invasive candidiasis. Invasive candidiasis is a fungal infection caused by a yeast called *Candida* that has spread widely in the body and may also be present in the blood.

Invasive candidiasis is rare, and Rezzayo was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 January 2021. Further information on the orphan designation can be found on the EMA website.

Rezzayo contains the active substance rezafungin.

How is Rezzayo used?

Rezzayo can only be obtained with a prescription and treatment should be started by a doctor experienced in the management of invasive fungal infections.

The medicine is given once a week as an infusion (drip) into a vein lasting at least 1 hour. The duration of treatment depends on how the patient responds, but should continue for at least 2 weeks after the last day that *Candida* is found in the patient's blood.

The medicine should be used according to official guidance issued at national level on the use of antifungal agents.

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

How does Rezzayo work?

Rezafungin belongs to the group of antifungal medicines called echinocandins. It works by interfering with the production of a molecule called (1,3)-β-D-glucan, which strengthens the fungal cell wall. Treatment with rezafungin makes *Candida* cells fragile, causing them to die. This helps to bring invasive candidiasis under control and reduces damage from the disease.

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What benefits of Rezzayo have been shown in studies?

A main study involving 187 people with invasive candidiasis showed that Rezzayo was as effective as caspofungin (another antifungal medicine) in the treatment of invasive candidiasis. After 14 days of treatment, 59% (55 out of 93) of people who received Rezzayo had no signs or symptoms of *Candida* infection compared with 61% (57 out of 94) of those who received caspofungin.

Additional data showed that the rate of death due to any cause after 30 days of treatment was 24% (22 out of 93) for people treated with Rezzayo compared with 21% (20 out of 94) for those treated with caspofungin.

What are the risks associated with Rezzayo?

For the full list of side effects and restrictions with Rezzayo, see the package leaflet.

The most common side effects with Rezzayo (which may affect more than 1 in 10 people) include hypokalaemia (low blood potassium levels), fever and diarrhoea.

Rezzayo must not be used by people who are hypersensitive (allergic) to other echinocandin medicines or to any of the ingredients of Rezzayo (which are listed in the package leaflet).

Why is Rezzayo authorised in the EU?

Rezzayo has been found to be as effective in treating invasive candidiasis as an authorised antifungal medicine of the same class, caspofungin. Although there was some uncertainty regarding the effectiveness of the medicine compared with that of caspofungin due to the relatively small number of patients in the study, additional data supported the main study outcome. In addition, Rezzayo is given once a week compared with once a day for other medicines of the same class. The safety profile of the medicine is in line with that of other medicines of the same class. The European Medicines Agency therefore decided that Rezzayo's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Rezzayo

Rezzayo received a marketing authorisation valid throughout the EU on 22 December 2023.

Further information on Rezzayo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rezzayo