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Zinplava (*bezlotoxumab*)

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

What is Zinplava and what is it used for?

Zinplava is a medicine used in adults and children from one year of age who have infections due to bacteria called *Clostridioides difficile* that cause severe diarrhoea. It is used to prevent future episodes of diarrhoea in patients who are taking antibiotics to treat their *C. difficile* infection and who are at high risk of the infection coming back.

Zinplava contains the active substance bezlotoxumab.

How is Zinplava used?

Zinplava is given as a single infusion (drip) into a vein lasting around 1 hour. The dose depends on the patient's bodyweight.

The medicine can only be obtained with a prescription. For further information, see the package leaflet or contact your doctor or pharmacist.

How does Zinplava work?

C. difficile bacteria produce toxins that damage the lining of the gut causing diarrhoea which may be severe. After an initial infection, some dormant forms of the bacteria (spores) may persist in the body and eventually produce further toxins, causing the symptoms to return. The active substance in Zinplava, bezlotoxumab, is a monoclonal antibody (a type of protein) that has been designed to attach to these toxins, blocking their action, thereby preventing further damage and diarrhoea from occurring.

What benefits of Zinplava have been shown in studies?

Zinplava given during antibiotic treatment was shown to be more effective than placebo (a dummy treatment) at preventing a new episode of diarrhoea caused by *C. difficile* infection in 2 main studies

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involving a total of 2,655 adults. A new episode of diarrhoea was defined as 3 or more loose stools in 24 or fewer hours.

In the first study, 17% of patients given Zinplava (67 out of 386) had a new episode of diarrhoea in the 12 weeks after treatment compared with 28% of patients given placebo (109 out of 395). In the second study, figures were 16% (62 out of 395) for Zinplava and 26% (97 out of 378) for placebo. The effect was mainly seen in patients at higher risk of *C. difficile* infection coming back (such as older patients or those with a weakened immune system).

An additional study involving 148 children between the ages of one and 17 years showed that the safety of Zinplava and the way the medicine is absorbed, modified and removed from the body in children are consistent with those seen in adults. In the study, 11% of children given Zinplava (11 out of 98) had a new episode of diarrhoea in the 12 weeks after treatment, compared with 15% of children given placebo (5 out of 34).

What are the risks associated with Zinplava?

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

The most common side effects with Zinplava (seen in more than 4 in 100 patients) are nausea (feeling sick), diarrhoea, fever and headache. Similar effects have been seen in patients on placebo.

Why is Zinplava authorised?

Zinplava has been shown to be effective at preventing recurrence of *C. difficile* infection, particularly in patients at high risk of the infection coming back (which occurs in about 15 to 35% of cases and is particularly difficult to treat). Zinplava is generally well tolerated with side effects similar to those observed in patients on placebo.

The European Medicines Agency therefore decided that Zinplava's benefits are greater than its risks and recommended that it be authorised in the EU.

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

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

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

Other information about Zinplava

Zinplava received a marketing authorisation valid throughout the EU on 18 January 2017.

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

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