EMA/201086/2017
EMEA/H/C/004136

EPAR summary for the public

Zinplava

bezlotoxumab

This is a summary of the European public assessment report (EPAR) for Zinplava. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zinplava.

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

What is Zinplava and what is it used for?

Zinplava is a medicine used in adults who have infections due to bacteria called *Clostridium 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.

How is Zinplava used?

Zinplava is available as a concentrate to be made into a solution for infusion (drip) into a vein. It is given as a single infusion lasting around 1 hour. The recommended dose is 10 mg per kilogram bodyweight.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

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. Bezlotoxumab is a monoclonal

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 involving a total of 2,655 patients. 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).

What are the risks associated with Zinplava?

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.

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

Why is Zinplava approved?

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 Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Zinplava's benefits are greater than its risks and recommended that it be approved for use 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.

Other information about Zinplava

The European Commission granted a marketing authorisation valid throughout the European Union for Zinplava on 18 January 2017.

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

This summary was last updated in 01-2017.