

Zinplava[™] (bezlotoxumab) – New Drug Approval

- On October 21, 2016, Merck announced the FDA approval of Zinplava (bezlotoxumab) injection, to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.
 - Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug and should only be used in conjunction with antibacterial drug treatment of CDI.
- CDI is caused by bacteria that produce toxins, including toxin B. Symptoms of CDI include mild-tosevere diarrhea, abdominal pain, and fever. The incidence of recurrent CDI is higher in certain populations, including people 65 years of age and older and those with compromised immune systems.
- Zinplava is a sterile, preservative-free solution containing bezlotoxumab, a human monoclonal antibody that binds to C. difficile toxin B. Binding to toxin B neutralizes its effects.
- The safety and efficacy of Zinplava were evaluated in two placebo-controlled trials in 1,613 adult patients receiving standard of care antibacterial drugs for treatment of CDI. After achieving a clinical cure with antibacterial therapy, patients were evaluated for recurrence of CDI through 12 weeks following administration of Zinplava or placebo.
 - In the first trial, 60.1% of patients in the Zinplava arm achieved a sustained clinical response vs. 55.2% in the placebo arm (95% CI: -2.1, 11.7)
 - In the second trial, 66.8% of patients in the Zinplava arm achieved a sustained clinical response vs. 52.1% in the placebo arm (95%CI: 7.7, 21.4).
- The Warnings and Precautions section of Zinplava includes heart failure.
- The most common adverse events ($\geq 4\%$) with Zinplava use were nausea, pyrexia, and headache.
- The recommended dose of Zinplava is a single dose of 10 mg/kg given as an intravenous infusion over 60 minutes.
 - Zinplava should be administered during antibacterial drug treatment for CDI.
 - Zinplava should be administered via a low protein binding 0.2 micron to 5 micron in-line or add-on filter.
 - The safety and efficacy of repeat administration of Zinplava in patients with CDI have not been studied.
- Merck plans to launch Zinplava in the first quarter of 2017. Zinplava will be available as a 1,000 mg/40 mL (25 mg/mL) solution in a single-dose vial.



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