

Patient Information
ZINPLAVA™ (zin-PLAH-va)
(bezlotoxumab)
injection, for intravenous use

What is ZINPLAVA?

ZINPLAVA is a prescription medicine used to help decrease the risk of C-diff (*Clostridioides difficile* infection) from coming back in adults and children 1 year of age and older who are taking an antibiotic for C-diff and who have a high risk of C-diff coming back.

ZINPLAVA is not used to treat C-diff and is not an antibiotic. ZINPLAVA should only be used along with the antibiotic that you are taking to treat C-diff. Keep taking your antibiotic for your C-diff as directed by your doctor.

It is not known if ZINPLAVA is safe and effective in children under 1 year of age.

Before receiving ZINPLAVA, tell your doctor about all of your medical conditions, including if you:

- have or have had congestive heart failure (CHF).
- are pregnant or trying to get pregnant. It is not known if ZINPLAVA will harm your unborn baby. You and your doctor should decide together if you will receive ZINPLAVA.
- are breastfeeding or plan to breastfeed. It is not known if ZINPLAVA passes into your breast milk. You and your doctor should decide together if you will receive ZINPLAVA.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive ZINPLAVA?

- You will receive ZINPLAVA into your vein through an IV (intravenously).
- You do not need to do anything to prepare for receiving ZINPLAVA.
- You will receive ZINPLAVA in 1 dose and it will take about 1 hour.
- If you miss your appointment, call your doctor right away to reschedule it.

What are the possible side effects of ZINPLAVA?

ZINPLAVA may cause serious side effects, including:

- **Heart failure.** Heart failure may happen in people who receive ZINPLAVA and can be serious. People with a history of congestive heart failure (CHF) who received ZINPLAVA had a higher rate of heart failure and death than those who did not receive ZINPLAVA.

Common side effects of ZINPLAVA:

The most common side effects that may happen on the day of or the day after receiving ZINPLAVA include:

- | | |
|-----------------|-----------------------|
| • nausea | • shortness of breath |
| • headache | • feeling dizzy |
| • fever | • high blood pressure |
| • feeling tired | |

The most common side effects that may happen up to four weeks after receiving ZINPLAVA include:

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| • nausea | • headache |
| • fever | |

If you have any side effect that bothers you or does not go away, tell your doctor.

These are not all the possible side effects of ZINPLAVA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ZINPLAVA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or doctor for information about ZINPLAVA that is written for health professionals.

What are the ingredients in ZINPLAVA?

The active ingredient is: bezlotoxumab

The inactive ingredients are: citric acid monohydrate, diethylenetriaminepentaacetic acid, polysorbate 80, sodium chloride, sodium citrate dihydrate, and water for injection, USP. ZINPLAVA may also contain sodium hydroxide.

For more information, call the company that makes ZINPLAVA, at 1-800-444-2080, or go to the website – www.ZINPLAVA.com. You can also find the full prescribing information written for health professionals at www.ZINPLAVA.com

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At:
MSD Ireland (Carlow)
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For patent information: www.msd.com/research/patent

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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