

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

What you need to know about ZINPLAVA

- Before you receive ZINPLAVA, be sure you understand what it is for and how it is given.
- ZINPLAVA helps decrease the risk of C-diff (*Clostridium difficile* infection) from coming back by working with the antibiotic that you are taking to treat your C-diff. ZINPLAVA does not replace the antibiotic. ZINPLAVA is not an antibiotic.
- Keep taking your antibiotic for your C-diff as directed by your doctor.
- If you have questions about ZINPLAVA, ask your doctor or pharmacist.
- Keep this Patient Information for ZINPLAVA so you can read it again.

What is ZINPLAVA?

ZINPLAVA is a prescription medicine used to help decrease the risk of C-diff from coming back in people 18 years of age or older who are taking an antibiotic for C-diff and who have a high risk of C-diff coming back.

C-diff is a bacterial infection that can damage your colon and cause stomach pain and severe diarrhea. When people get C-diff, they often take an antibiotic to get rid of the infection. Even when treated by an antibiotic, C-diff can come back within weeks to months. ZINPLAVA helps to decrease the risk of the infection from coming back. It works when given along with the antibiotic that you are taking to treat C-diff.

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.

Is ZINPLAVA right for me?

Children

- It is not known if ZINPLAVA is safe and effective in children under 18 years old.

Pregnancy

- If you are pregnant or trying to get pregnant, tell your doctor before you receive ZINPLAVA.
- It is not known if ZINPLAVA will harm your baby while you are pregnant.
- You and your doctor should decide together if you will receive ZINPLAVA.

Breastfeeding

- If you are breastfeeding or plan to breastfeed, tell your doctor before you receive ZINPLAVA.
- It is not known if ZINPLAVA gets in your breast milk and will be passed to your baby.
- You and your doctor should decide together if you will receive ZINPLAVA.

Medical Conditions

- Tell your doctor about any medical conditions you have now or have had before.
- Make sure to tell your doctor if you have or have had congestive heart failure (CHF).

Other Medicines

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

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:

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

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

- nausea
- fever
- headache

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

There may be other side effects to ZINPLAVA that are not listed. 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 the Patient Information. You can ask your pharmacist or doctor for information about ZINPLAVA that is written for doctors.

What if I have questions?

- Call your doctor.
- Call Merck, the company that makes ZINPLAVA, at 1-800-444-2080.
- Go to the website – www.ZINPLAVA.com
You can also find the full prescribing information written for doctors at www.ZINPLAVA.com

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.

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

Manufactured by: Merck Sharp & Dohme Corp., a subsidiary of
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At:
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For patent information: www.merck.com/product/patent/home.html

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