

ZINPLAVA®

Concentrated Injection

Bezlotoxumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZINPLAVA. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having ZINPLAVA against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What ZINPLAVA is used for

ZINPLAVA contains the active ingredient bezlotoxumab.

ZINPLAVA is a medicine to prevent *Clostridium difficile* infection (CDI) from coming back in adults who are taking an antibiotic for CDI and have a high risk of CDI coming back.

CDI is a bacterial infection that can damage your colon and cause stomach pain and severe diarrhoea.

When people get CDI, they often take an antibiotic to get rid of the infection. Even when treated with antibiotics, CDI can come back within weeks to months.

ZINPLAVA prevents the infection coming back. It works when given

along with your antibiotic that you are taking for CDI.

Ask your doctor if you have any questions about why ZINPLAVA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given ZINPLAVA

When you must not be given it

You must not be given ZINPLAVA if you have an allergy to:

- bezlotoxumab
- any of the ingredients listed at the end of this leaflet

ZINPLAVA should not be used in children below 18 years of age until more information becomes available.

Before you are given it

- **Tell your doctor if you have any allergies to any other medicines, or any other substances such as foods, preservatives or dyes.**
- **Tell your doctor if you have or have had congestive heart failure (CHF)**
- **Tell your doctor if you are pregnant, think you may be pregnant or trying to become pregnant.**

It is unknown if ZINPLAVA will harm your baby while you are pregnant. Your doctor can

discuss with you the risks and benefits involved.

- **Tell your doctor if you are breastfeeding.**
Your doctor can discuss with you the risks and benefits involved.
- **Keep taking your antibiotic for CDI as directed by your doctor.**
ZINPLAVA works with your antibiotic that you are taking for CDI. ZINPLAVA is not an antibiotic. It does not replace it.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

How ZINPLAVA is given

- ZINPLAVA is given as an infusion or "drip" injection into your vein (intravenously) for about 1 hour.
- You do not need to do anything to prepare for getting ZINPLAVA.
- ZINPLAVA will be given once during a course of antibiotic therapy for *Clostridium difficile* infection (CDI).

While you are being treated with ZINPLAVA

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given ZINPLAVA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given ZINPLAVA.

Side effects

Like all medicines, ZINPLAVA can cause side effects, although not everyone gets them.

ZINPLAVA may cause serious side effects, including:

- heart failure (symptoms include shortness of breath, tiredness, swollen legs and rapid heartbeat)

The following side effects have been reported in clinical trials in adults:

Side effects of ZINPLAVA that can occur within 24 hours:

- tiredness
- headache
- fever
- feeling sick (nausea)
- shortness of breath
- dizziness
- high blood pressure

These are common (may affect up to 1 in 10 people).

Side effects of ZINPLAVA that can occur up to 4 weeks:

- feeling sick (nausea)
- diarrhoea
- fever
- headache

These are common (may affect up to 1 in 10 people).

Tell your doctor promptly if you notice any of the above side effects or any other side effects.

ZINPLAVA may cause other side effects that are not listed. For more information, ask your doctor.

Ask your doctor to answer any questions you may have.

Storing ZINPLAVA

Storage

It is unlikely that you will be asked to store ZINPLAVA yourself. It will usually be stored in the pharmacy or on the ward.

Product description

What it looks like

ZINPLAVA is a clear to moderately opalescent, colourless to pale yellow liquid in a glass vial.

Ingredients

Active ingredient:

- bezlotoxumab

Inactive ingredients:

- citric acid monohydrate
- pentetic acid
- polysorbate 80
- sodium chloride
- sodium citrate dihydrate
- Water for Injections
- May contain sodium hydroxide to adjust the pH to 6.0.

Sponsor

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