Package leaflet: Information for the patient

ZINPLAVA® 25 mg/mL concentrate for solution for infusion
bezlotoxumab

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ZINPLAVA is and what it is used for

ZINPLAVA contains the active substance bezlotoxumab.

ZINPLAVA is a medicine that is given together with an antibiotic to prevent *Clostridium difficile* infection (CDI) from coming back in patients 18 years of age or older who have a high risk of CDI coming back.

How ZINPLAVA works
- When people get CDI, they are usually given an antibiotic to get rid of the infection, but CDI can often come back within weeks or months.
- The bacteria responsible for CDI produce a toxin that can inflame and damage your colon, causing stomach pain and severe diarrhoea. ZINPLAVA acts by attaching to the toxin and blocking it, thereby preventing the symptoms of CDI from coming back.

2. What you need to know before you are given ZINPLAVA

Talk to your doctor before you are given ZINPLAVA.

You should not be given ZINPLAVA if:
- you are allergic to bezlotoxumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
ZINPLAVA is not a treatment for CDI. ZINPLAVA has no effect on the CDI you have now.

ZINPLAVA is given with the antibiotic therapy you are taking for CDI.

Children and adolescents
ZINPLAVA should not be used in children and adolescents below 18 years of age.

Other medicines and ZINPLAVA
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
- If you are pregnant or trying to get pregnant, tell your doctor.
- We don't know if ZINPLAVA will harm your baby while you are pregnant.
- If you are breast-feeding or are planning to breast-feed, check with your doctor first.
- We don't know if ZINPLAVA gets in your breast milk and is passed to your baby.
- You and your doctor should decide together if you will use ZINPLAVA.

Driving and using machines
ZINPLAVA has no or very little effect on the ability to drive and use machines.

ZINPLAVA contains sodium
This medicine contains 182.8 mg sodium (main component of cooking / table salt) in each vial. This is equivalent to 9.1 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How you are given ZINPLAVA
- You will get ZINPLAVA as an infusion (drip) into a vein.
- You will get ZINPLAVA in one dose and it will take about 1 hour. Your dose will be calculated using your body weight.
- You should keep taking your antibiotic for CDI as directed by your doctor.

If you miss an appointment to get ZINPLAVA
- Call your doctor or healthcare professional right away to reschedule your appointment.
- It is very important that you do not miss the dose of this medicine.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported in clinical trials:

Common (may affect up to 1 in 10 people)
- diarrhoea
- dizziness
- feeling sick (nausea)
- fever
- headache
- high blood pressure
- shortness of breath
- tiredness

Tell your doctor or health care professional if you notice any of the side effects above.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ZINPLAVA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator 2 °C to 8 °C. Do not freeze. Keep vial in the outer carton in order to protect from light.

The diluted solution of ZINPLAVA may be stored either at room temperature for up to 16 hours or under refrigeration at 2 °C to 8 °C for up to 24 hours. If refrigerated, allow the IV bag to come to room temperature prior to use.

Do not store any unused portion of the infusion solution for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What ZINPLAVA contains
- The active substance is bezlotoxumab. Each mL of concentrate contains 25 mg of bezlotoxumab.
- The other ingredients are citric acid monohydrate (E330), diethylenetriaminepentaacetic acid, polysorbate 80 (E433), sodium chloride, sodium citrate dihydrate (E331), water for injections, and sodium hydroxide (E524) (for pH adjustment).

What ZINPLAVA looks like and contents of the pack
The concentrate for solution for infusion is a clear to moderately opalescent, colourless to pale yellow liquid.
It is available in cartons containing one glass vial.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in Great Britain: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK

Marketing Authorisation Holder in UK (Northern Ireland): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Manufacturer
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For any information about this medicine, please contact:

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This leaflet was last revised in September 2021.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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The following information is intended for healthcare professionals only:

Preparation of diluted solution

- Prepare the diluted solution immediately after removal of the vial(s) from refrigerated storage, or the vial(s) may be stored at room temperature protected from light for up to 24 hours prior to preparation of the diluted solution.
- Inspect vial contents for discoloration and particulate matter prior to dilution. ZINPLAVA is a clear to moderately opalescent, colourless to pale yellow liquid. Do not use the vial if the solution is discoloured or contains visible particles.
- Do not shake the vial.
- Withdraw the required volume from the vial(s) based on the patient's weight (in kg) and transfer into an IV bag containing either 0.9 % Sodium Chloride Injection, or 5 % Dextrose Injection, to prepare a diluted solution with a final concentration ranging from 1 to 10 mg/mL. Mix diluted solution by gentle inversion.
- Discard vial(s) and all unused contents.
- If the diluted solution is refrigerated, allow the IV bag to come to room temperature prior to use.
- Do not freeze the diluted solution.

Method of administration

- Administer the diluted solution for infusion intravenously over 60 minutes using a sterile, non-pyrogenic, low-protein binding 0.2 micron to 5 micron in-line or add-on filter. ZINPLAVA should not be administered as an intravenous push or bolus.
- The diluted solution can be infused via a central line or peripheral catheter.
- ZINPLAVA must not be co-administered with other medicinal products simultaneously through the same infusion line.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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