Package leaflet: Information for the patient

Dalbavancin BE Pharma 500 mg powder for concentrate for solution for infusion
dalbavancin

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <invented name> is and what it is used for

<Invented name> contains the active substance dalbavancin, which is an **antibiotic** of the glycopeptide group.

<Invented name> is used to treat **adults and children from birth with infections of the skin or in the layers of flesh below the skin.**

<Invented name> works by killing certain bacteria, which can cause serious infections. It kills these bacteria by interfering with the formation of bacterial cell walls.

If you also have other bacteria that cause your infection, your doctor may decide to treat you with other antibiotics in addition to <invented name>.

2. What you need to know before you are given <invented name>

Do not use <invented name> if you are **allergic** to dalbavancin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given <invented name>:
- If you have or have had **kidney problems**. Depending on your age and the condition of your kidney, your doctor may have to reduce your dose.
- If you are suffering from **diarrhoea**, or you have previously suffered from diarrhoea when being treated with antibiotics.
- If you are **allergic** to other antibiotics such as vancomycin or teicoplanin.

<u>Diarrhoea during or after treatment</u>

If you develop **diarrhoea during** or **after** your treatment, tell your doctor **at once**. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Infusion-related reactions

Intravenous infusions with these types of antibiotics can cause flushing of the upper body, hives, itching and/or rashes. If you experience these types of reactions your doctor may decide to stop or slow the infusion.

Other infections

Using antibiotics may sometimes allow a new and different infection to develop. If this happens tell your doctor and they will decide what to do.

Other medicines and <invented name>

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

Pregnancy and breast-feeding

<Invented name> is not recommended during pregnancy unless clearly necessary. This is because it is not known what effect it might have on an unborn baby. Before you are given this medicine, tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. You and your doctor will decide if you will be given <invented name>.

It is not known if <invented name> passes into breast milk in humans. Ask your doctor for advice before breast-feeding your baby. You and your doctor will decide if you will be given <invented name>. You should not breastfeed when given <invented name>.

Driving and using machines

<Invented name> may cause dizziness. Take care with driving and using machines after you have been given this medicine.

<Invented name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How you will be given <invented name>

<Invented name> will be given to you by a doctor or nurse.

- **Adults:** <invented name> is given in a single dose of 1,500 mg or in two doses a week apart: 1,000 mg on Day 1 and 500 mg on Day 8.
- **Children and adolescents aged from 6 years to less than 18 years:** <invented name> is given in a single dose of 18 mg/kg (maximum 1,500 mg).
- **Infants and children aged from birth to less than 6 years:** <invented name> is given in a single dose of 22.5 mg/kg (maximum 1,500 mg).

The dose for children aged from birth to less than 18 years will be calculated by the doctor based on the age and weight of the child.

You will be given <invented name> through a drip directly into your bloodstream through a vein (intravenously) over 30 minutes.

Patients with chronic kidney problems

If you suffer from chronic kidney problems, your doctor may decide to reduce your dose. There is not enough information to recommend the use of <invented name> for children with chronic kidney problems.

If you are given more <invented name> than you should

Tell your doctor or nurse immediately if you are concerned that you may have been given too much <invented name>.

If you miss a dose of <invented name>

Tell your doctor or nurse immediately if you are concerned that you are missing the 2nd dose.

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

4. Possible side effects

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

Serious side effects

Tell your doctor straight away if you get any of these symptoms - you may need urgent medical attention:

- **Sudden swelling of your lips, face, throat or tongue; severe rash; itchiness; throat tightening; drop in blood pressure; difficulty in swallowing and /or difficulty in breathing.** These may all be signs of a hypersensitivity reaction and may be life-threatening. This severe reaction has been reported as a rare side effect**.** It may affect up to 1 in 1,000 people.
- **Abdominal pain (stomach ache)** and/or **watery diarrhoea**. The symptoms may become severe or may not go away and the stools may contain blood or mucus. These may be signs of an infection of the bowel. In this situation, you should **not** take medicines that stop or slow bowel movement. Infection of the bowel has been reported as an uncommon side effect. It may affect up to 1 in 100 people.
- **Changes in hearing**. This has been reported as a side effect with a similar medicine. The frequency is not known. The frequency cannot be estimated from the available data.

Other side effects reported with <invented name> are listed below.

Talk to your doctor, pharmacist or nurse if you get any of the following side effects:

Common - may affect up to 1 in 10 people:

- Headache
- Feeling sick (nausea)
- Diarrhoea

Uncommon - may affect up to 1 in 100 people:

- Vaginal infections, fungal infections, oral thrush
- Urinary tract infections
- Anaemia (low levels of red blood cells), high blood platelet counts (thrombocytosis), increased blood counts of a type of white blood cell called eosinophils (eosinophilia), low levels of other types of white blood cell (leucopenia, neutropenia)

- Changes in other blood tests
- Decreased appetite
- Difficulty sleeping
- Dizziness
- Change in sense of taste
- Inflammation and swelling of surface veins, flushing
- Cough
- Abdominal pain and discomfort, indigestion, constipation
- Abnormal liver function test
- An increase in alkaline phosphatase (an enzyme found in the body)
- Itching, hives
- Genital itching (females)
- Pain, redness or swelling at the place where the infusion was given
- Feeling hot
- Increase in blood levels of gamma-glutamyl transferase (an enzyme produced by the liver and other body tissues)
- Rash
- Being sick (vomiting)

Rare - may affect up to 1 in 1,000 people:
- Difficulty breathing (bronchospasm)

Reporting of side effects

If you get **any side effects**, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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 vial after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions if kept unopened in the original container.

The prepared <invented name> solution for infusion must not be used if there are any particles or the solution is cloudy.

<Invented name> is for single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <invented name> contains
- The active substance is dalbavancin. Each vial of powder contains dalbavancin hydrochloride equivalent to 500 mg of dalbavancin.
- The other ingredients are mannitol (E421), lactose monohydrate, hydrochloric acid and/or sodium hydroxide (for pH adjustment only).

What <invented name> looks like and contents of the pack

<Invented name> powder for concentrate for solution for infusion is provided in a 50 ml type I glass vial with a bromobutyl rubber stopper and aluminium seal with green polypropylene flip top. The vial contains white to off-white to pale yellow powder.
It is available in pack containing 1 vial.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 2026-05-27

The following information is intended for healthcare professionals only: Important:

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

<Invented name> must be reconstituted with sterile water for injections and subsequently diluted with 50 mg/ml (5 %) glucose solution for infusion.

<Invented name> vials are for single-use only.

Instructions for reconstitution and dilution

Aseptic technique must be used for reconstitution and dilution of <invented name>.

1. The content of each vial must be reconstituted by slowly adding 25 ml of water for injection.
2. **Do not shake.** To avoid foaming, alternate between gentle swirling and inversion of the vial, until its contents are completely dissolved. The reconstitution time may be up to 10 minutes.
3. The reconstituted concentrate in the vial contains 20 mg /ml dalbavancin.
4. The reconstituted concentrate must be a clear, colourless to yellow solution with no visible particles.
5. The reconstituted concentrate must be further diluted with 50 mg/ml (5 %) glucose solution for infusion.
6. To dilute the reconstituted concentrate, the appropriate volume of the 20 mg/ml concentrate must be transferred from the vial to an intravenous bag or bottle containing 50 mg/ml (5 %) glucose solution for infusion. For example: 25 ml of the concentrate contains 500 mg dalbavancin.
7. After dilution the solution for infusion must have a final concentration of 1 to 5 mg/ml dalbavancin
8. The solution for infusion must be clear, colourless to yellow solution with no visible particles.
9. If particulate matter or discoloration is identified, the solution must be discarded.

<Invented name> must not be mixed with other medicinal products or intravenous solutions. Sodium chloride containing solutions can cause precipitation and should NOT be used for reconstitution or dilution. The compatibility of reconstituted <invented name> concentrate has only been established with 50 mg/ml (5 %) glucose solution for infusion.

If a common intravenous line is being used to administer other medicinal products in addition to <invented name>, the line should be flushed before and after each <invented name> infusion with 5 % glucose solution for infusion.

Use in the paediatric population

For paediatric patients, the dose of <invented name> will vary according to the age and weight of the child up to a maximum of 1,500 mg. Transfer the required dose of reconstituted dalbavancin solution, according to the instructions above, based on the child's weight, from the vial to an intravenous bag or bottle containing 50 mg/ml (5 %) glucose solution for infusion. The diluted solution must have a final dalbavancin concentration of 1 to 5 mg/ml.

Table 1 below provides information to prepare an infusion solution with a final concentration of 2 mg/ml or 5 mg/ml (sufficient for most scenarios), to be administered by syringe pump, to achieve a dose of 22.5 mg/kg in paediatric patients from birth to 12 months of age weighing from 1 to 12 kg. Alternative concentrations may be prepared, but must have a final concentration range of 1 to 5 mg/ml of dalbavancin. Refer to Table 1 to confirm the calculations. Values shown are approximate. Note that the table is NOT inclusive of all possible calculated doses for every age group but may be utilised to estimate the approximate volume to verify the calculation.

Table 1. Preparation of <invented name> (final infusion concentration 2 mg/ml or 5 mg/ml to be administered by syringe pump) in paediatric patients aged birth to 12 months (22.5 mg/kg dose)

Patient Weight (kg)	Dose (mg) to achieve 22.5 mg/kg	Volume of reconstituted dalbavancin solution (20 mg/ml) to be withdrawn from vial (ml)	Volume of diluent 50 mg/ml (5 %) glucose solution to add for mixing (ml)	Final dalbavancin infusion solution concentration	Total Volume Dosed by syringe pump (ml)
1	22.5	10 ml	90 ml	2 mg/ml	11.3
2	45.0				22.5
3	67.5				33.8
4	90.0				45.0
5	112.5				56.3
6	135.0				67.5
7	157.5				78.8
8	180.0				90.0
9	202.5	20 ml	60 ml	5 mg/ml	40.5
10	225.0				45.0
11	247.5				49.5
12	270.0				54.0

Disposal

Discard any portion of the reconstituted solution that remains unused.

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