Package leaflet: Information for the user

Dalbavancin Baxter 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 Dalbavancin Baxter is and what it is used for
2. What you need to know before you are given Dalbavancin Baxter
3. How you will be given Dalbavancin Baxter
4. Possible side effects
5. How to store Dalbavancin Baxter
6. Contents of the pack and other information

1. What Dalbavancin Baxter is and what it is used for

Dalbavancin Baxter contains the active substance dalbavancin, which is an antibiotic of the glycopeptide group.
Dalbavancin Baxter is used to treat **adults and children from birth with infections of the skin or in the layers of flesh below the skin**.

This medicine 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 Dalbavancin Baxter.

2. What you need to know before you are given Dalbavancin Baxter

Do not use Dalbavancin Baxter 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 Dalbavancin Baxter:
- 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.

Diarrhoea during or after treatment
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 Dalbavancin Baxter
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
Dalbavancin Baxter 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 this medicine.

It is not known if this medicine 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 Dalbavancin Baxter. You should not breastfeed when given this medicine.

Driving and using machines
Dalbavancin Baxter may cause dizziness. Take care with driving and using machines after you have been given this medicine.

Dalbavancin Baxter 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 Dalbavancin Baxter
Dalbavancin Baxter will be given to you by a doctor or nurse.

- **Adults:** this medicine 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 :** this medicine 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 :** this medicine 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 this medicine 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 Dalbavancin Baxter for children with chronic kidney problems.

If you are given more Dalbavancin Baxter than you should
Tell your doctor or nurse immediately if you are concerned that you may have been given too much Dalbavancin Baxter.

If you miss a dose of Dalbavancin Baxter.
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 Dalbavancin Baxter 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 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 Dalbavancin Baxter

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 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 Dalbavancin Baxter solution for infusion must not be used if there are any particles or the solution is cloudy.

Dalbavancin Baxter 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 Dalbavancin Baxter 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 1N and/or sodium hydroxide 1N (for pH adjustment only).

What Dalbavancin Baxter looks like and contents of the pack
Dalbavancin Baxter powder for concentrate for solution for infusion is provided in a single-use 53 ml clear transparent glass vial with a chlorobutyl stopper and a red aluminium flip off seal. The vial contains white to off-white to pale yellow powder.

It is available in carton packs containing 1 vial.

Marketing Authorisation Holder

Baxter Healthcare Limited
Caxton Way,
Thetford, Norfolk, IP24 3SE,
United Kingdom

Manufacturer
Famar Health Care Services Madrid S.A.U
Avenida de Leganés, 62, Poligono Industrial Urtinsa I
28923 Alcorcón, Madrid. Spain

Detailed information on this medicine is available on the website of the UK Medicines and Healthcare Products Regulatory Agency

This leaflet was last revised in July 2025

Baxter

07-19-00-8444

The following information is intended for healthcare professionals only:

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

Dalbavancin Baxter must be reconstituted with sterile water for injections and subsequently diluted with 50 mg/ml (5%) glucose solution for infusion.

Dalbavancin Baxter vials are for single-use only.

Instructions for reconstitution and dilution
Aseptic technique must be used for reconstitution and dilution of Dalbavancin Baxter
1. The content of each vial must be reconstituted by slowly adding 25 ml of water for injections.
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 5 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.

Dalbavancin Baxter 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 Dalbavancin Baxter 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 Dalbavancin Baxter,the line should be flushed before and after each Dalbavancin Baxter infusion with 5% glucose solution for infusion.

Use in the paediatric population
For paediatric patients, the dose of Dalbavancin Baxter 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 Dalbavancin Baxter (final infusion concentration 2 mg/ml or 5 mg/ml to be administered by syringe pump) in paediatric patients from 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.