



Dalbavancin hydrochloride (Xydalba®)

Information for clinicians

Dalbavancin is a black triangle medicine \mathbf{V} which means it is subject to additional monitoring. *Any suspected adverse reactions must be reported using the yellow card system*

Dalbavancin is a glycopeptide antibacterial with bactericidal activity against Gram +ve bacteria. Each vial contains dalbavancin 500mg

Indication As per GHC LRTI antimicrobial guidelines during Covid-19 Pandemic

Dosing:

Adults (18 years and over)

1500 mg administered as either a single infusion of 1500 mg Or

1000 mg as an infusion followed one week later by 500 mg

Elderly - No dose adjustment is necessary

Renal impairment - Dose adjustments are not required for patients with mild or moderate renal impairment (creatinine clearance between 30 to 79 ml/min).

Dose adjustments are not required for patients receiving regularly scheduled haemodialysis (3 times/week), and dalbavancin may be administered without regard to the timing of haemodialysis.

In patients with chronic renal impairment whose creatinine clearance is LESS THAN 30 ml/min and who are not receiving regularly scheduled haemodialysis, the recommended dose is reduced to either 1000 mg administered as a single infusion or 750 mg followed one week later by 375 mg

Hepatic impairment - No dose adjustment of dalbavancin is recommended for patients with mild hepatic impairment

moderate or severe hepatic impairment - caution should be exercised when prescribing as no data are available to determine appropriate dosing



Dalbavancin must be reconstituted and then further diluted prior to administration by intravenous infusion over a 30 minute period. **IMPORTANT - dilute with Glucose 5% solution NOT Sodium chloride 0.9%**

Aseptic technique must be used for reconstitution and dilution

- The content of each vial must be reconstituted by slowly adding 25 ml of water for injections.
- **Do not shake** to try and prevent foaming reconstitute in a drop-wise fashion, down the inside of the vial glass, rolling gently to disperse and dissolve (do not shake) until contents are completely dissolved, giving a colourless to yellow solution. This may take up to 5 minutes
- The reconstituted concentrate in the vial contains 20 mg/ml dalbavancin
- The reconstituted concentrate must be a clear, colourless to yellow solution with no visible particles
- The reconstituted concentrate must be further diluted with 5% (50mg/ml) glucose solution for infusion. To do this the appropriate volume of the 20 mg/ml concentrate must be transferred from the vial to an intravenous bag containing 5% glucose solution for infusion.
- After dilution the solution for infusion must have a final concentration of 1-5 mg/ml dalbavancin

For example:

25 mL of the reconstituted concentrate contains 500 mg dalbavancin.

Dilute 25ml (500mg) of concentrate in 250ml Glucose 5% to give a concentration of 2mg/mL

Dilute 2 x 25ml (1g) of concentrate in 250ml Glucose 5% to give a concentration of 4mg/mL

- The solution for infusion must be clear, colourless to yellow solution with no visible particles.
- If particulate matter or discoloration is identified, the solution must be discarded.



Administration

- Administer via a pump
- Give by IV infusion over 30 minutes to minimise the risk of infusion-related reactions (red-man syndrome)
- The infusion has a low pH and may cause venous irritation and tissue damage in cases of extravasation.
- If a central venous access device is unavailable, administer via a large peripheral vein monitoring insertion site closely using a recognised phlebitis scoring tool.
- Resite cannula at first signs of inflammation.

After administration flush with glucose 5% (incompatible with sodium chloride 0.9%)

Adverse effects

Rapid administration can cause 'red-man'-like syndrome (upper body flushing, urticaria, pruritus, rash). Other adverse effects include hypersensitivity reactions, nausea, diarrhoea and headache. Monitor for infusion-related reactions; slow or stop the infusion if they occur.

Hypersensitivity reactions

Dalbavancin should be administered with caution in patients known to be hypersensitive to other glycopeptides since cross-hypersensitivity may occur. If an allergic reaction to dalbavancin occurs, administration should be discontinued and appropriate therapy for the allergic reaction should be instituted.

Pregnancy and lactation

- Dalbavancin is not recommended during pregnancy unless clearly necessary.
- Not enough evidence is available to confirm if administration is safe for breast feeding mothers. Breast feeding should be discontinued during administration of dalbavancin and for 7 days after treatment

Side effects

The most common adverse reactions

- Nausea
- Diarrhoea
- Headache