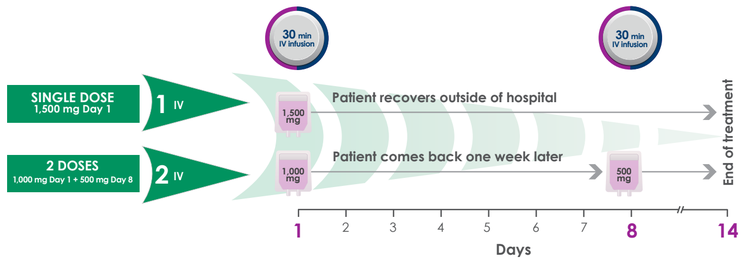
Xydalba™

Dalbavancin 500 mg

ADVANZ PHARMA

EASY ADMINISTRATION

2 dose regimens to fit with your preferred treatment approach:



- Recommended dose in adults: **1,500 mg.**
- Administered over **30 minutes by intravenous infusion**.
- **No monitoring required:** TDM (Therapeutic Drug Monitoring), Blood cell, or CPK (creatinine phosphokinase).
- **No dose adjustment,** except for patients with severe renal impairment not on regular hemodialysis (decrease dose: a single 30-minute IV infusion of 1,000 mg or an infusion of 750 mg followed by a second infusion of 375 mg on Day 8).
- **Well tolerated:** Only 3 common AEs: Nausea 2.4%, Diarrhoea 1.9%, Headache 1.3%.

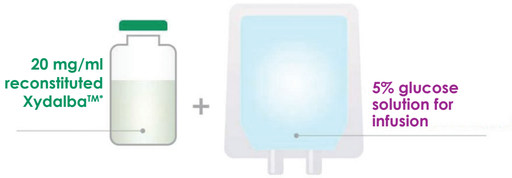
STEP 1 : RECONSTITUTION

Sodium chloride *containing solutions can cause precipitation and* ***SHOULD NOT*** *be used for reconstitution or dilution of Xydalba™.*

- Each vial is for a **single-use only**.

- Reconstitute by **slowly adding 25 mL of sterile water** for injection.
- **Do not shake.** To avoid excessive foaming, **alternate between, gentle swirling with inversion of the vial** to completely dissolve the Xydalba™. The reconstitution time may be up to 5 minutes.
- The reconstituted concentrate in the vial contains **20 mg/mL** Xydalba™.
  The reconstituted concentrate must be a **clear, colourless to yellow solution** with no visible particles.

STEP 2 : DILUTION



The final solution for infusion must have a Xydalba™* concentration of 1 to 5 mg/ml

*Reconstituted Xydalba™ should be a clear, colourless to yellow solution with no visible particles.

Transfer the adequate volume of the reconstituted concentrate to an intravenous bag or bottle containing 50 mg/ml (5%) glucose solution for infusion.

Xydalba™ must not be mixed with other medicinal products or intravenous solutions. If a common intravenous line is being used to administer other medicinal products in addition to Xydalba, the line should be flushed before and after each Xydalba infusion with 5% glucose solution for infusion.

Dilution Dalbavancin Dose	Volume (ml) of reconstituted dalbavancin concentrate (20 mg/ml)	Minimum volume (ml) of 5% glucose solution for infusion (5 mg/ml)	Maximal volume (ml) of 5% glucose solution for infusion (1 mg/ml)
375 mg	19	56	356
500 mg	25	75	475
750 mg	38	113	713
1,000 mg	50	150	950
1,500 mg	75	225	1,425

ADMINISTRATION

- The final solution for infusion must have a Xydalba™ concentration of 1 to 5 mg/ml.
- **Sodium chloride** containing solutions can cause precipitations and **SHOULD NOT** be used for reconstitution or dilution of Xydalba™.
- **Reconstituted Xydalba™ should be a clear, colourless to yellow solution.**

STORAGE

- Dry powder: 4 years. This medicinal product does not require any special storage conditions.
- The total in-use stability from reconstitution to administration should not exceed 48 hours at or below 25 °C.
- From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions. Do not freeze.

INDICATION

Xydalba™ is indicated for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Please consult the Summary of Product Characteristics (SmPC) for further information including adverse effects (available on: https://www.medicines.org.uk/emc/product/2270/smpc#gref). Or scan the QR code.

Reference: Xydalba™ SmPC, 12/2022.

PRESCRIPTION ONLY MEDICINE.
Price: £558.70 per 500mg vial.
Marketing authorisation holder: AbbVie Ltd., Maidenhead, SL6 4UB, UK **Marketing authorisation number:** PLGB 41042/0086. **Date of revision of the text:** April 2022.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to ADVANZ PHARMA medical information: Tel: +44 (0) 208 588 9131; Email: medicalinformation@advanzpharma.com.

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