PRESCRIPTION INFORMATION
Xydalba 500 mg powder for concentrate for solution for infusion
(Dalbavancin hydrochloride)

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

Presentation: Each vial contains dalbavancin hydrochloride equivalent to 500mg dalbavancin. After reconstitution each ml contains 20mg dalbavancin. The diluted solution for infusion must have a final concentration of 1-5mg/ml dalbavancin.
Indication: For the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older.
Dosage and administration: *Method of administration:* Intravenous use. *Adults:* 1,500 mg administered as either a single infusion of 1,500 mg or as 1,000 mg followed one week later by 500 mg. *Elderly:* No dose adjustment is necessary. In adult patients with chronic renal impairment whose creatinine clearance is <30 ml/min and who are not receiving regularly scheduled haemodialysis, reduced dose recommended to either 1,000 mg administered as a single infusion or 750 mg followed one week later by 375 mg. There is insufficient information to recommend dosage adjustment for patients younger than 18 years with creatinine clearance less than 30 ml/min/1.73 m^2. Caution should be exercised when prescribing dalbavancin to patients with moderate or severe hepatic impairment (Child-Pugh B & C) as no data are available to determine appropriate dosing. *Children and adolescents aged from 6 years to less than 18 years: single dose of 18 mg/kg (maximum 1,500 mg). Infants and children aged from 3 months to less than 6 years: single dose of 22.5 mg/kg (maximum 1,500 mg). Xydalba must be reconstituted and then further diluted prior to administration by IV infusion over a 30-minute period.*
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Special warnings and precautions for use: 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. *Clostridioides* (formerly *Clostridium*) *difficile*-associated diarrhoea: Antibacterial-associated colitis and pseudomembranous colitis have been reported with the use of nearly all antibiotics and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the treatment with dalbavancin. In such circumstance, the discontinuation of dalbavancin and the use of supportive measures together with the administration of specific treatment for *Clostridioides* (formerly *Clostridium*) *difficile* should be considered. These patients must never be treated with medicinal products that suppress the peristalsis. Infusion related reactions: Rapid infusions of glycopeptide agents can cause reactions that resemble "Red-Man Syndrome", including flushing of the upper body, urticaria, pruritus, and/or rash. Stopping or slowing the infusion may result in cessation of these reactions. Renal impairment: Information on the efficacy and safety of dalbavancin in patients with creatinine clearance < 30 ml/min is limited. Based on simulations, dose adjustment is needed for patients with chronic renal impairment whose creatinine clearance is < 30 ml/min and who are not receiving regular haemodialysis. Mixed Infections: In mixed infections in which Gram-negative bacteria are suspected patients should also be treated with an appropriate antibacterial agent(s) against Gram negative bacteria. Non-susceptible organisms: The use of antibiotics may promote the overgrowth of non-susceptible micro-organisms. If superinfection occurs during therapy, appropriate measures should be taken. Limitations of the clinical data: There is limited data on safety and efficacy of dalbavancin when administered for more than two doses (one week apart). In the major trials in ABSSSI the types of infections treated were confined to cellulitis/erysipelas, abscesses and wound infections only. There is no experience with dalbavancin in the treatment of severely immunocompromised patients. Excipient: This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'. Incompatibilities: Sodium chloride solutions may cause precipitation and must not be used for reconstitution or dilution.
Interaction: Co-administered CYP inducers or inhibitors are unlikely to influence the pharmacokinetics of dalbavancin. Co-administration with inhibitors of hepatic uptake and efflux transporters may increase the exposure to dalbavancin. Examples of such transporter inhibitors are boosted protease inhibitors, verapamil, quinidine, itraconazole, clarithromycin and cyclosporine. Increased exposure to transporter

substrates sensitive for inhibited transporter activity, such as statins and digoxin, cannot be excluded if combined with dalbavancin.
Pregnancy and lactation: Not recommended during pregnancy, unless the potential expected benefit clearly justifies the potential risk to the foetus. Continue/discontinue therapy with Xydalba taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Undesirable effects: *Common:* occurring in ≥ 1% of patients treated with dalbavancin were nausea (2.4%), diarrhoea (1.9%), and headache (1.3%) and were generally of mild or moderate severity. (Please refer to the Summary of Product Characteristics for detailed information).
Overdose: Treatment of overdose with dalbavancin should consist of observation and general supportive measures. Although no information is available specifically regarding the use of haemodialysis to treat overdose, it should be noted that in a Phase 1 study in patients with renal impairment, less than 6 % of the recommended dalbavancin dose was removed after 3 hours of haemodialysis.
Legal category: POM
Basic Price: Single-use 48 ml type I glass vial with an elastomeric stopper and a green flip off seal. Each pack contains 1 vial. UK: £558.70 per 500mg vial.
Marketing authorisation number: PLGB 41042/0086
Marketing authorisation holder: AbbVie Ltd, Maidenhead, SL6 4UB, UK (Distributed by: ADVANZ PHARMA: Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK.
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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/Adverse events should also be reported to **Advanz Pharma Medical Information** via telephone on +44 (0) 208 588 9131 or via e-mail at **medicalinformation@advanzpharma.com**