Refer to the Full Prescribing Information which can be obtained from your representative or from the EMEA website http://www.ema.europa.eu.

PRESCRIPTION ONLY MEDICINE.

Product name: Xydalba 500 mg powder for concentrate for solution for infusion. **Presentation:** Each vial contains dalbavancin hydrochloride equivalent to 500 mg dalbavancin. **Therapeutic indications:** Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. **Posology:** The recommended dose of dalbavancin in adult patients with ABSSSI is 1500 mg administered as either a single infusion of 1500 mg or as 1000 mg followed one week later by 500 mg. In patients with chronic renal impairment whose creatinine clearance is < 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. 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. **Paediatric *population:*** The safety and efficacy of dalbavancin in children aged from birth to < 18 years has not yet been established. **Method of administration:** Xydalba must be reconstituted and then further diluted prior to administration by intravenous infusion over a 30 minute period. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** Xydalba should be administered with caution in patients known to be hypersensitive to other glycopeptides since cross-hypersensitivity may occur. If an allergic reaction to Xydalba occurs, administration should be discontinued and appropriate therapy for the allergic reaction should be instituted. **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 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. **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. 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. **Interaction with other medicinal products:** No known drug interactions. Clinical drug-drug interaction studies with dalbavancin have not been conducted. Dalbavancin is not metabolised by CYP enzymes in vitro, therefore co-administrated use of CYP inhibitors or inducers is unlikely to influence the pharmacokinetics of dalbavancin. **Undesirable effects:** The most common adverse reactions 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. Consult the SmPC for information on less common side effects. **Incompatibilities:** Sodium chloride solutions may cause precipitation and must not be used for reconstitution or dilution. This medicinal product must not be mixed with other medicinal products or intravenous solutions other than those stated.

Packaging, quantity and price (excluding VAT): Single-use 48 ml type I glass vial with an elastomeric stopper and a green flip off seal. Each pack contains 1 vial.

Price: £558.70 per 500mg vial.

Marketing authorisation holder: Allergan Pharmaceuticals International Ltd., Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland.

Marketing authorisation number: EU/1/14/986/001.

Date of revision of the text: December, 2018

Adverse events should be reported:

▼ This medicinal product is subject to additional monitoring

Forms and information can be found at: **www.mhra.gov.uk/yellowcard**. Adverse events should also be reported to: Correvio UK Ltd Tel: **+44 (0)203 002 8114; email:medinfo@correvio.com**