One dose of Xydalba™ provides:

- Potent activity against Gram-positive pathogens, including multi-resistant strains[13]
- Effective treatment for patients with comorbidities (e.g. elderly, obese, diabetic or vulnerable patients)[5,9-12]

With:

- No dose adjustments, except for severe renal impairment[1*]
- No monitoring of TDM (Therapeutic Drug Monitoring), blood cell, or CPK (creatinine phosphokinase)[1]
- Low potential for drug-drug interactions[1**]
- No weight-based dosing[1]

1 dose of Xydalba™ gives your patients 2 weeks of effective treatment in a single 30-minute infusion[1]

= Less days in hospital[2,3]

*Caution should be exercised when prescribing Xydalba™ to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) as no data are available to determine the appropriate dosing in these patients.[1]
**Clinical drug-drug interaction studies with dalbavancin have not been conducted.[1]

PI & AE Reporting

Please consult the Summary of Product Characteristics (SmPC) for further information including adverse effects (available on: www.ema.europa.eu).

PRESCRIPTION ONLY MEDICINE. **Name of the medicinal product:** Xydalba™ (dalbavancin hydrochloride) 500 mg powder for concentrate for solution for infusion. **Presentation:** White to off-white to pale yellow powder for concentrate for solution for infusion. 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. **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 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. 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:* The safety and efficacy of dalbavancin in children aged from birth to < 18 years has not yet been established. 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:** *In vitro* receptor screening study do not indicate a likely interaction with other therapeutic targets or a potential for clinically relevant pharmacodynamic interactions. 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:** *Serious:* Anaphylactoid reaction, bronchospasm, *Clostridioides* (formerly *Clostridium*) *difficile* colitis and phlebitis. *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. Ireland: 760€ per 500mg vial.

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

Marketing authorisation holder: Allergan Pharmaceuticals International Ltd., Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland. (Distributed by: ADVANZ PHARMA: Capital House, 1st Floor, 85 King William Street, London EC4N 7BL, UK.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (UK) or www.hpra.ie (IE). Adverse events should also be reported to Advanz Pharma Medical Information via telephone on **+44 0 8700 70 30 33** (UK) or **1890 25 24 73** (IE) or via e-mail at **medicalinformation@advanzpharma.com**

References: 1. Xydalba™ (dalbavancin) Summary of Product Characteristics. **2.** Marcellusi A, *et al.* Economic evaluation of the treatment of acute bacterial skin and skin structure infections (ABSSSIs) from the national payer perspective: introduction of a new treatment to the patient journey. A simulation of three European countries. Expert Rev Pharmacoecon Outcomes Res. 2019;4:1-19. **3.** McCarthy MW, *et al.* Dalbavancin reduces hospital stay and improves productivity for patients with Acute Bacterial Skin and Skin Structure Infections: The ENHANCE Trial. Infect Dis Ther. 2020;9:53-67. **4.** Data on file. FDA Briefing Presentation. Anti-infective Drugs Advisory Committee Meeting. NDA 21-883. March 31, 2014. **5.** Boucher HW, *et al.* Once-Weekly Dalbavancin versus Daily Conventional Therapy for Skin Infection. N Engl J Med. 2014;370:2169-79. **6.** Dunne MW, *et al.* Safety of Dalbavancin in the Treatment of Skin and Skin Structure Infections: A Pooled Analysis of Randomized, Comparative Studies. Drug Safety. (2016) 39:147–157. **7.** Dunne, *et al.* A Randomized Clinical Trial of Single Dose vs Weekly Dalbavancin for Treatment of Acute Bacterial Skin and Skin Structure Infection. Clin Infect Dis. 2016;62:545-51. **8.** Rappo, *et al.* Single-Dose Dalbavancin and Patient Satisfaction in an Outpatient Setting in the Treatment of Acute Bacterial Skin and Skin Structure Infections. Journal of Global Antimicrobial Resistance. 2019;17:60–65. **9.** Dunne M and Puttagunta S. Dalbavancin for the treatment of complicated skin and soft tissue infections in patients with and without diabetes mellitus in the DISCOVER studies. Poster presented at ECCMID 2014, May 10–13, 2014, Barcelona, Spain. **10.** Puttagunta S and Dunne M. Dalbavancin for the treatment of acute bacterial skin and skin structure infections in obese patients. Poster presented at ECCMID, Copenhagen, Denmark 25-28 April 2015. **11.** Soriano A, *et al.* The role of dalbavancin in the treatment of acute bacterial skin and skin structure infections (ABSSSIs)Expert Review of Anti-infective Therapy 2020;18(5):415-422. **12.** XYDALBA™ Assessment report EMA/39820/2015. **13.** Streit JM, *et al.* Activity against selected populations of antimicrobial-resistant Gram-positive pathogens. Diagn Microbiol Infect Dis. 2005 Dec;53(4):307-10.

ADVANZ PHARMA

For healthcare professionals Only Date of preparation: July 2021 ADV/DAL/PM/0039

Want to learn more?

To find more information on ADVANZ PHARMA anti-infective products, please visit:

www.advanzdigitalhub.com

One dose does it.*

Xydalba™ delivers two weeks of effective treatment in a single dose,[1] meaning your patients can spend less days in hospital.[2,3]

Xydalba™
Dalbavancin 500 mg

Less really is more

*Clinical success achieved in 90% of patients (in Discover studies)[5]. Xydalba™ is indicated for the treatment of ABSSSI in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.[1]

1.

One dose offers ...

- Ease-of-use[1]
- More time and resources for you[2,3]
- Less risk of nosocomial infections[2]
- Less days in hospital for your patients[2,3]

2.

Two weeks of treatment ...

- Fast (2-3 days) and long-lasting efficacy[1,4]
- Fewer adverse events than comparators[5*,6**]
- Less concern about compliance[4,7]
- Less catheter related risks[2,7]

*Vancomycin/linezolid in Discover studies.[5] **Pooled analysis of dalbavancin-treated patients in phase 2/3 studies vs. those receiving comparator agents (vancomycin, linezolid, cefazolin, nafcillin, or oxacillin).[6]

3.

In a 30-minute infusion.

- More patient satisfaction[8]
- Patients experience few constraints on their daily activities[8]
- Improved convenience for you[2,3]

Xydalba™
Dalbavancin 500 mg
Less really is more