Xydalba™
500 mg
(dalbavancin hydrochloride)
powder for infusion

A different approach to treating vulnerable and challenging patients suffering from serious skin infections

Each year there are more than 290,000 cases of serious skin infections in the UK, with 79% receiving IV antibiotics as a first line treatment.[i]

Hospital admission is often unavoidable, cellulitis alone accounts for 8% of emergency admissions.[ii] Outpatient therapy is often not suitable for all patients and adherence to oral antibiotic can be low, resulting in poor clinical outcomes.[iii]

There is now a different approach to how these patients can be treated – Xydalba™ (dalbavancin hydrochloride) is a full course of IV antibiotic that can be administered in a single 30-minute infusion.[iv,v]

Xydalba is approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.[v] It can be given in one or two doses and offers the opportunity for patients to be treated and discharged on the same day.[vi] In a key study, Xydalba successfully treated a majority of patients as outpatients.[iv]

Xydalba is particularly useful in treating those patients that can be challenging for clinical staff when they present to accident and emergency (A&E) departments:

- The elderly and frail who may be unable to attend hospital daily for IV therapy and therefore have to be admitted.
- Patients with dementia suffering from confusion, unpredictable behaviours, with a risk of falls, or decline in their health status that makes admittance high-risk.
- IV drug user (IVDU) patients who can sometimes be problematic, present a high risk of needle stick injuries, and cannot be left with a PICC line in, which may be abused by self-injecting into it or could possibly be pulled and dislodged leaving part of the line in the patient, which could be fatal. A recent study showed similar efficacy of Xydalba in IVDU and non-IVDU patients.[vii]
- Homeless patients who are excluded from the OPAT service due to having no fixed address and therefore have to be admitted.
- Obese patients who have mobility issues and require high doses of treatment.

Said Dr John Cunniffe, Consultant in Medical Microbiology: "Xydalba offers opportunities that you don't have with existing treatments for ABSSSI. It means that patients who aren't suitable for daily outpatient therapy can be treated, and patients who would otherwise be in a hospital bed can be turned around relatively quickly.

"Xydalba is a simple, convenient regime which is generally well tolerated by the patient, easy to use because a full course of treatment can be delivered with a single 30-minute infusion and is also easy for staff to administer."

"Because accident and emergency departments are under particular pressure, Xydalba enables patients to be treated and discharged, therefore reducing pressure on departments and in-patient beds."

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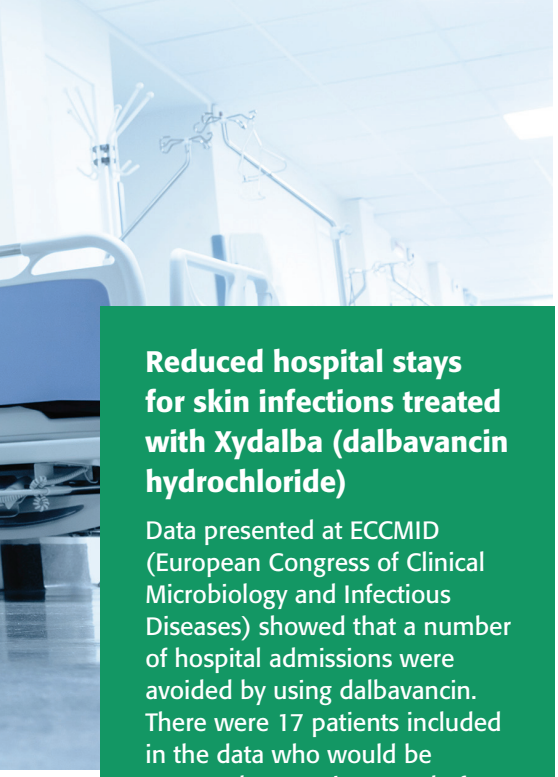

Reduced hospital stays for skin infections treated with Xydalba (dalbavancin hydrochloride)

Data presented at ECCMID (European Congress of Clinical Microbiology and Infectious Diseases) showed that a number of hospital admissions were avoided by using dalbavancin. There were 17 patients included in the data who would be expected to require a total of 119 hospital days; this was reduced to 13 by using dalbavancin, representing a possible saving of £53,000.[viii] Included in the data were a number of challenging patients, some of whom were IVDUs and obese patients.

References

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[iv] Dunne MW, Talbot GH, Boucher HW, Wilcox M, Puttagunta S. Safety of Dalbavancin in the Treatment of Skin and Skin Structure Infections: A Pooled Analysis of Randomized, Comparative Studies. Drug Saf. 2016 Feb;39(2):147-57 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4735234/pdf/40264_2015_Article_374.pdf

[v] Xydalba™ Summary of Product Characteristics https://www.medicines.org.uk/emc/medicine/32656

[vi] Dunne MW, Puttagunta S, Giordano P, Krievins D, Zelasky M, Baldassarre J. 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(5):545-551 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4741365/pdf/civ982.pdf

[vii] Gonzalez PL, Rappo U, Akinapelli K, McGregor J S, Puttagunta S, Dunne MW. Treatment of acute bacterial skin and skin structure infection with single-dose dalbavancin in persons who inject drugs. Drugs in Context 2018; 7: 212559. https://doi.org/10.7573/dic.212559)

[viii] Laing R, Falconer S. Reduced Hospital Stays for Skin Infections Treated with Dalbavancin. ECCMID 2018, Madrid, Spain. Abstract Publication PO282 https://www.escmid.org/escmid_publications/escmid_elibrary/?q=dalbavancin&L=0&x=22&y=23

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

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