

Dalvance® (dalbavancin) – Expanded indication

- On July 23, 2021, <u>AbbVie announced</u> the <u>FDA approval</u> of <u>Dalvance (dalbavancin)</u>, for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (including *S. anginosus*, *S. intermedius*, *S. constellatus*) and *Enterococcus faecalis* (vancomycin susceptible isolates).
 - Dalvance was previously approved in adults only.
- The approval of Dalvance for the expanded indication was based on an open-label, randomized, actively controlled study in 191 pediatric patients with ABSSSI, not known or expected to be caused exclusively by Gram-negative organisms. Patients were randomized to receive either Dalvance single-dose regimen, Dalvance two-dose regimen, or comparator. The comparator regimens included intravenous (IV) vancomycin for methicillin-resistant Gram-positive infections, or IV oxacillin or flucloxacillin for methicillin-susceptible Gram-positive infection. Primary endpoints included: (1) early clinical response at 48 to 72 hours, defined as ≥ 20% reduction in lesion size compared to baseline and no receipt of rescue antibacterial therapy; and (2) clinical cure, defined as resolution of the clinical signs and symptoms of infection, when compared to baseline, and no additional antibacterial treatment for the disease under study.
 - The proportion of patients with early clinical response was 97.3% in the Dalvance single-dose arm, 93.6% in the Dalvance two-dose arm, and 86.7% in the comparator arm. The difference in responder rates between the Dalvance single-dose and comparator arms was 10.7% (97.5% CI: -1.7, 31.6). The difference in responder rates between the Dalvance two-dose and comparator arms was 6.9% (97.5% CI: -6.4, 27.7).
 - The clinical cure rate at the test of cure visit was 94.7% in the Dalvance single-dose arm, 92.3% in the Dalvance two-dose arm and 100% in the comparator arm. The difference in cure rates between the Dalvance single-dose and comparator arms was -5.3% (97.5% CI: -15.1, 10.5). The difference in cure rates between the Dalvance two-dose and comparator arms was -7.7% (97.5% CI: -17.9, 8.3).
- The most common adverse reaction (> 1%) with Dalvance use in pediatric patients was pyrexia.
- The recommended dosage regimen of Dalvance in pediatric patients with estimated creatinine clearance (CLcr) 30 mL/min/1.73m² and above is a single dose regimen based on the age and weight of the pediatric patient. Dalvance is administered over 30 minutes by IV infusion.
 - In pediatric patients from birth to less than 6 years, the recommended dosage is 22.5 mg/kg (maximum 1500 mg). In pediatric patients 6 to less than 18 years of age, the recommended dosage is 18 mg/kg (maximum 1500 mg).
 - Refer to the Dalvance drug label for adult dosing.



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