Dalvance®
(dalbavancin) for injection
500 mg

NOW APPROVED
FOR PEDIATRIC PATIENTS
from birth to <18 years

providing a full course of therapy for your pediatric patients with ABSSSI[1]

INDICATION AND USAGE

DALVANCE® (dalbavancin) for injection is indicated for the treatment of pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of 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).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial agents, DALVANCE should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications

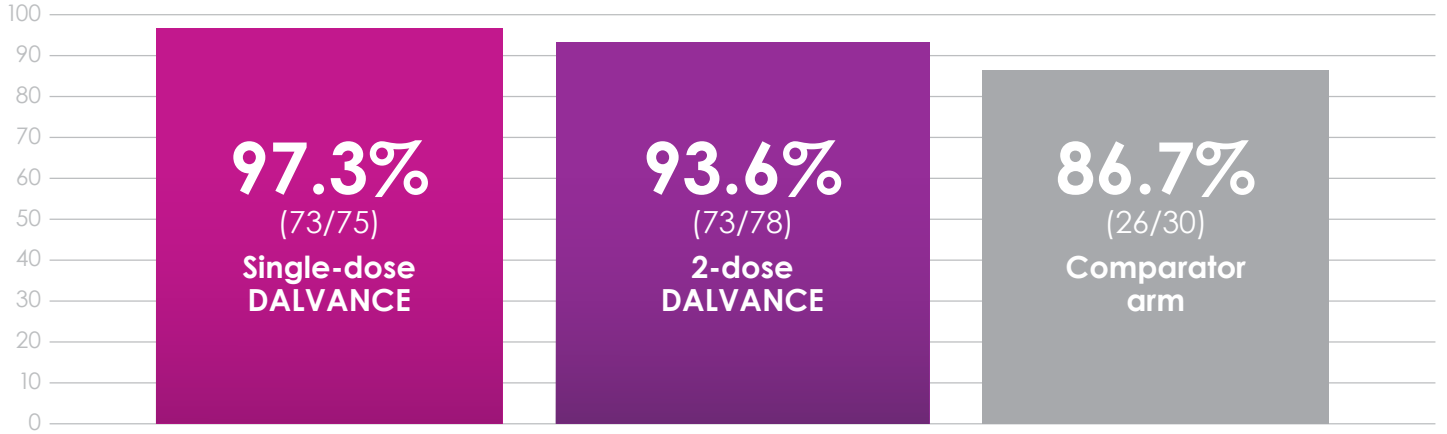
DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit
https://www.rxabbvie.com/pdf/dalvance_pi.pdf

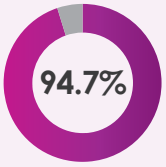
DALVANCE® NOW APPROVED FOR PEDIATRIC PATIENTS FROM BIRTH TO <18 YEARS

Early clinical response demonstrated at 48-72 hours[1]

Clinical response at 48-72 hours (mITT)



- Clinical response was a secondary endpoint; the primary objective of the study was to evaluate the safety and tolerability of DALVANCE. The trial was not powered for a comparative inferential efficacy analysis



Sustained efficacy: Clinical cure rate was **94.7% (71/75)** at the TOC visit (28 ± 2 days) for patients receiving single-dose DALVANCE.

Early clinical response at 48-72 hours was defined as ≥20% reduction in lesion size compared to baseline and no receipt of rescue antibacterial therapy.

Clinical cure was 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 mITT population (N=183) included all randomized patients who received any dose of study drug and had a diagnosis of ABSSSI caused by Gram-positive organism(s). The five patients in the age group birth to <3 months of age were not included in efficacy analyses since they were enrolled with expanded inclusion criteria and only received the single-dose DALVANCE regimen.

mITT, modified intent-to-treat; TOC, test of cure.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Hypersensitivity Reactions

Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE. Exercise caution in patients with known hypersensitivity to glycopeptides due to the possibility of cross-sensitivity. If an allergic reaction occurs, treatment with DALVANCE should be discontinued.

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/dalvance_pi.pdf

Dalvance® (dalbavancin) for injection 500 mg

Safety and tolerability in pediatric patients[1]

The most common adverse reaction occurring in **>1%** of pediatric patients was pyrexia: 1.2% (2/161)

Adverse reactions reported in **<1%** of pediatric patients treated with DALVANCE

Diarrhea | Dizziness | Pruritus

Study design: A multicenter, open-label, randomized, actively controlled trial was conducted in pediatric patients 3 months of age to <18 years with ABSSSI not known or expected to be caused exclusively by Gram-negative organisms. Patients were randomized in a 3:3:1 ratio to receive either single-dose DALVANCE, the 2-dose DALVANCE regimen, or comparator. The comparator regimens included IV vancomycin for methicillin-resistant Gram-positive infections or IV oxacillin or flucloxacillin for methicillin-susceptible Gram-positive infections. Patients in the comparator arm received IV treatment for a minimum of 72 hours before an optional switch to oral therapy to complete a total of 10-14 days of antibacterial drug therapy. An additional 5 patients from birth to <3 months of age were enrolled and assigned to the DALVANCE single-dose regimen.[1]

Overall, the mean area of infection for ABSSSI was **79 cm²**, with over **70%** of patients experiencing **severe erythema** and **severe pain/tenderness** to palpation.[2]

IV, intravenous.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Infusion-related Reactions

Rapid intravenous infusion of DALVANCE can cause reactions, including flushing of the upper body, urticaria, pruritus, rash, and/or back pain.

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

***Clostridioides difficile*-associated Diarrhea**

Clostridioides difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Development of Drug-resistant Bacteria

Prescribing DALVANCE in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions in Pediatric Patients

The most common adverse reaction that occurred in more than 1% of pediatric patients was pyrexia (1.2%).

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit
https://www.rxabbvie.com/pdf/dalvance_pi.pdf

Dalvance® (dalbavancin) for injection 500 mg

DALVANCE® NOW APPROVED FOR PEDIATRIC PATIENTS FROM BIRTH TO <18 YEARS

The only single-dose, 30-minute infusion providing a full course of therapy[1]

Recommended dosage in pediatric patients (CLcr ≥30 mL/min/1.73m^2)

Age range	Dosage (single-dose DALVANCE)
Birth to <6 years	22.5 mg/kg (maximum 1500 mg)
6 to <18 years	18 mg/kg (maximum 1500 mg)

There is insufficient information to recommend dosage adjustment for pediatric patients <18 years with CLcr <30 mL/min/1.73m^2.

CLcr, creatinine clearance.

IMPORTANT SAFETY INFORMATION (continued)

Use in Specific Populations

- There are no adequate and well-controlled studies with DALVANCE use in pregnant or nursing women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DALVANCE and any adverse effects on the breast-fed child from DALVANCE or from the underlying maternal condition.
- In patients with renal impairment whose known creatinine clearance (CLcr) is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis, the recommended regimen of DALVANCE is 1125 mg, administered as a single dose, or 750 mg followed one week later by 375 mg. No dosage adjustment is recommended for patients receiving regularly scheduled hemodialysis, and DALVANCE can be administered without regard to the timing of hemodialysis. There is insufficient information to recommend dosage adjustment for pediatric patients younger than 18 years of age with CLcr less than 30 mL/min/1.73m^2.
- Caution should be exercised when prescribing DALVANCE 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.

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit
https://www.rxabbvie.com/pdf/dalvance_pi.pdf

Dalvance®
(dalbavancin) for injection
500 mg

References: 1. DALVANCE® (dalbavancin) [prescribing information]. Madison, NJ: Allergan USA, Inc.; 2021. **2.** Data on file. Allergan, Inc.

abbvie