Dalvance®
(dalbavancin) for injection
500 mg

www.DALVANCE.com

Consider moving beyond daily IV infusions

DALVANCE®: The only 1-dose, 30-minute IV antibiotic option for ABSSSI[1]

One 30-minute 1500 mg infusion* provides a full course of outpatient antibiotic treatment for ABSSSI[1]

The Only 1 Dose

30 Minute Infusion

- No therapeutic drug monitoring required
- No PICC line required

ABSSSI=acute bacterial skin and skin structure infections.
PICC=peripherally inserted central catheter.

No recommended dosage adjustment for many patient populations[1]

Patient types	Obese patients	Geriatric patients†	Hepatic impairment patients‡	Renal impairment patients with CrCl ≥30 mL/mins*	Patients on regularly scheduled hemodialysis*	Patients with end-stage renal disease
No dosage adjustments recommended	✔	✔	✔	✔	✔	✔

†DALVANCE is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

‡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.

*Dosage in patients with normal or impaired renal function[1]

Estimated CrCl	1-dose DALVANCE	2-dose DALVANCE
≥30 mL/min or on regular hemodialysis	1500 mg	1000 mg followed 1 week later by 500 mg
<30 mL/min and not on regular hemodialysis	1125 mg	750 mg followed 1 week later by 375 mg

CrCl=creatinine clearance.

INDICATION AND USAGE

DALVANCE® (dalbavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus* group (including *S. anginosus, S. intermedius, S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible strains).

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 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 reverse side for additional Important Safety Information.
Please also see accompanying full Prescribing Information at the back of this pad.

abbvie

DALVANCE® is a long-acting agent with no known drug-drug interactions

Minimal drug-drug interactions with CYP450 enzymes[1]

- There is minimal potential for drug-drug interactions between DALVANCE and cytochrome P450 (CYP450) substrates, inhibitors, or inducers. No clinical drug-drug interaction studies have been conducted with DALVANCE
- Lessens the need to adjust treatment based on drug interactions involving the CYP450 system

No interaction with routinely used anticoagulant tests[1]

- DALVANCE at therapeutic levels does not artificially prolong prothrombin time or activated partial thromboplastin time

No therapeutic drug monitoring required[1]

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.

Infusion-related Reactions

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

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

Clostridium difficile-associated Diarrhea

Clostridium 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 is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%).

Use in Specific Populations

- There have been no adequate and well-controlled studies with DALVANCE in pregnant or nursing women. DALVANCE should only be used if the potential benefit justifies the potential risk in these populations.
- In patients with renal impairment whose known creatinine clearance 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.
- 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.

Reference: 1. DALVANCE® (dalbavancin) [prescribing information]. Madison, NJ: Allergan USA, Inc.; 2018.

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