Dalvance®

Provides a full course of ABSSSI treatment in just a single 30-minute infusion

Change the Treatment Journey

The Only SINGLE Dose

30 Minute Infusion

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 additional Important Safety Information throughout. Please also see full Prescribing Information.

Dalvance®
(dalbavancin) for injection
500 mg

Reduce exposure to the healthcare system for patients with ABSSSI

Urgent need exists to adopt effective treatment strategies that reduce hospitalizations[1]

ABSSSI* PATIENTS WHO MAY BE APPROPRIATE CANDIDATES TO AVOID THE BURDEN OF INPATIENT TREATMENT INCLUDE THOSE WHO[1]:

Are hemodynamically stable†	Do not have signs or symptoms of necrotizing fasciitis‡	Have stable comorbidities§

*ABSSSI is defined as cellulitis/erysipelas, wound infection, and major cutaneous abscess with a minimum lesion area of 75 cm^2.

†No need for resuscitation; no sepsis.

‡Negative Lab Risk Index Score; lack of clinical signs such as severe sepsis, disproportionate pain, rapid advancement of infection, and evidence of soft tissue gas, compartment syndrome, or muscle necrosis.

§No diabetic ketoacidosis or acute exacerbation of another disease.

ALLOCATION OF US COSTS BY DEPARTMENT FOR TREATING ABSSSI IN AN INPATIENT SETTING[2]

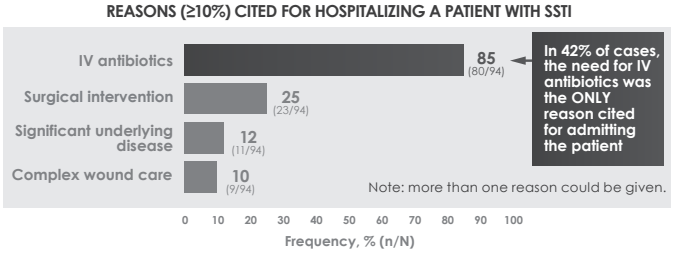
Over 50% of ABSSSI inpatient care costs were for room and board

Hospital costs and utilization were evaluated using a national hospital database for 2010 covering 99,798 hospital discharges with the principal diagnosis of ABSSSI after exclusion criteria were applied. Diagnoses and procedures were categorized according to ICD-9 and CPT codes current at the time. Average LOS was 5 days. The most frequent initial antibiotic treatments included vancomycin, piperacillin/tazobactam, clindamycin, linezolid, daptomycin, and tigecycline.[2]

CPT, Current Procedural Terminology; ICD-9, International Classification of Diseases, 9th revision; LOS, length of stay.

For many patients, the only reason for hospital admission is the need for IV antibiotics

NEED FOR IV ANTIBIOTICS IS THE MOST COMMON REASON TO ADMIT PATIENTS WITH SKIN AND SOFT TISSUE INFECTIONS (SSTI)[3]



Long-acting antibiotics are key to helping patients reduce exposure to the healthcare system[4]

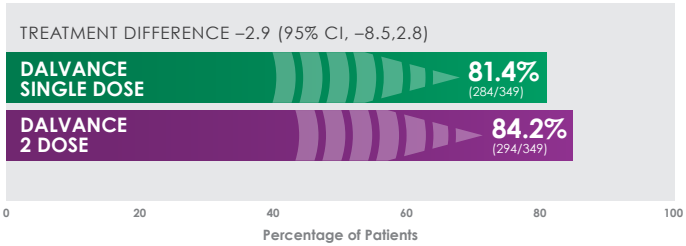
"The fact that administration of intravenous (IV) antibiotics is the sole reason for 42% of SSTI hospital admissions suggests that ***restructuring healthcare delivery away from the inpatient setting, as well as use of long-acting antibiotics****...may help to alleviate a substantial proportion of costs."*

—Kaye KS et al. *Clinical Infectious Diseases*, 2019

In ABSSSI, DALVANCE® may reduce patient exposure to the healthcare system:

A single 30-minute infusion provided early clinical response[5]

AT 48 TO 72 HOURS, SINGLE-DOSE DALVANCE DEMONSTRATED RESPONSE RATES SIMILAR TO THE 2-DOSE REGIMEN (ITT POPULATION)*



- Single-dose DALVANCE was shown to be noninferior to the 2-dose regimen

Please see single-dose study design on pages 18 and 19.

***Primary endpoint:** Clinical response defined as patients who had at least a 20% decrease from baseline in lesion area 48 to 72 hours after randomization without receiving any rescue antibiotic treatment.

CI, confidence interval; ITT, intent to treat.

Early clinical response against *S. aureus* and other key ABSSSI pathogens[5]

≥20% REDUCTION IN LESION SIZE AT 48 TO 72 HOURS†

	DALVANCE SINGLE DOSE	DALVANCE 2 DOSE
Baseline pathogen	**% (n/N)**	**% (n/N)**
Staphylococcus aureus	**88.5** (123/139)	**85.3** (133/156)
MSSA	**89.3** (92/103)	**89.6** (89/96)
MRSA	**86.1** (31/36)	**78.7** (48/61)
Streptococcus agalactiae	**100.0** (6/6)	**66.7** (4/6)
Streptococcus anginosus group	**93.9** (31/33)	**100.0** (19/19)
Streptococcus pyogenes	**100.0** (14/14)	**81.8** (18/22)
Enterococcus faecalis	**100.0** (4/4)	**80.0** (8/10)

†Efficacy outcome by baseline pathogen based on primary endpoint.

When ABSSSI involved bacteremia…

- **85%** (34/40) of DALVANCE patients with baseline bacteremia were clinical responders at 48 to 72 hours and **80%** (32/40) were clinical successes at Days 26 to 30‡[5]

‡In the single-dose trial and DISCOVER trials, all patients had blood cultures obtained at baseline. A total of 40 ABSSSI patients who received DALVANCE had bacteremia at baseline caused by 1 or more of the following bacteria: *S. aureus* (n=26 [21 MSSA; 5 MRSA]), *S. agalactiae* (n=6), *S. pyogenes* (n=7), *S. anginosus* group (n=2), and *E. faecalis* (n=1).[5]

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, rash, and/or back pain.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

Clostridium difficile-associated Diarrhea

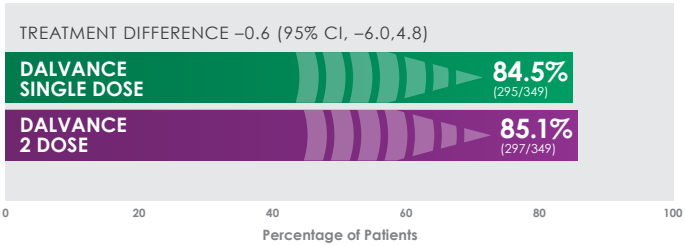
Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Dalvance® (dalbavancin) for injection 500 mg

In ABSSSI, DALVANCE® may reduce patient exposure to the healthcare system:

A single 30-minute infusion demonstrated clinical success at follow-up[5]

AT DAYS 26 TO 30, SINGLE-DOSE DALVANCE PROVIDED COMPARABLE CLINICAL SUCCESS RATES vs THE 2-DOSE REGIMEN (ITT POPULATION)*



Comparison of clinical success at Days 26 to 30 cannot be used to establish noninferiority.†

Please see single-dose study design on pages 18 and 19.

***Secondary endpoint:** Clinical success rate at follow-up visit (Days 26 to 30) was defined as having at least a 90% decrease from baseline in lesion size, a temperature of 37.6°C or lower, and meeting prespecified criteria for local signs: purulent discharge and drainage absent or mild and improved from baseline (for patients with wound infections), heat/warmth and fluctuance absent, swelling/induration and tenderness to palpation absent or mild.

†There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at the follow-up visit.

IMPORTANT SAFETY INFORMATION (continued)

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%).

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

Clinical success against *S. aureus* and other key ABSSSI pathogens[5]

CLINICAL SUCCESS AT DAYS 26 TO 30‡

	DALVANCE SINGLE DOSE	DALVANCE 2 DOSE
Baseline pathogen	**% (n/N)**	**% (n/N)**
Staphylococcus aureus	**89.2** (124/139)	**89.7** (140/156)
MSSA	**90.3** (93/103)	**89.6** (86/96)
MRSA	**86.1** (31/36)	**90.2** (55/61)
Streptococcus agalactiae	**83.3** (5/6)	**83.3** (5/6)
Streptococcus anginosus group	**87.9** (29/33)	**89.5** (17/19)
Streptococcus pyogenes	**92.9** (13/14)	**86.4** (19/22)
Enterococcus faecalis	**100.0** (4/4)	**90.0** (9/10)

‡Efficacy outcome by baseline pathogen based on primary endpoint.

IMPORTANT SAFETY INFORMATION (continued)

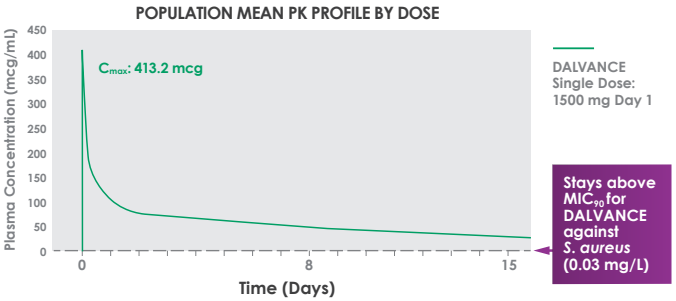
Use in Specific Populations

- 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.

Dalvance® (dalbavancin) for injection 500 mg

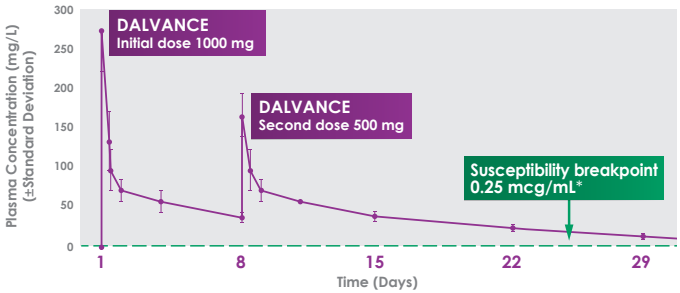
Predictable PK profile that remains above MIC level[2,6]

OVER TIME, PLASMA CONCENTRATION REMAINS ABOVE THE MIC_{90} FOR DALVANCE® AGAINST *S. AUREUS* FOR THE SINGLE-DOSE REGIMEN



C_{max}, peak concentration; MIC, minimum inhibitory concentration; PK, pharmacokinetic.

2-DOSE DALVANCE CONSISTENTLY STAYED ABOVE THE SUSCEPTIBILITY BREAKPOINT OF 0.25 mcg/mL UP UNTIL THE 14.4-DAY TERMINAL ELIMINATION HALF-LIFE[5]



*Susceptibility breakpoint for designated Gram-positive pathogens.

- No apparent accumulation of DALVANCE was observed following multiple IV infusions administered once weekly for up to 8 weeks, with 1000 mg on Day 1 followed by up to 7 weekly 500 mg doses, in healthy adults with normal renal function[5]

IMPORTANT SAFETY INFORMATION

Contraindications

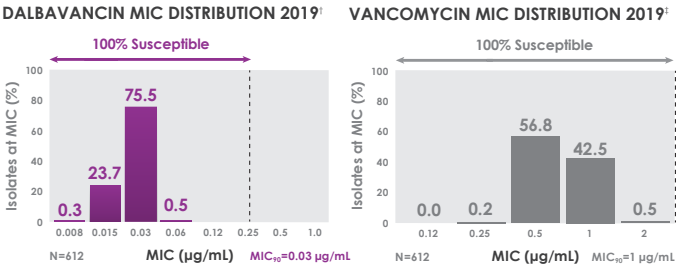
DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

IDEA: National surveillance data

100% of MRSA isolates were susceptible to dalbavancin at an MIC of 0.25 µg/mL[2]

MIC DISTRIBUTION OF DALBAVANCIN AND VANCOMYCIN (2019) vs MRSA SKIN ISOLATES[2]



Vancomycin is used as a surrogate to predict dalbavancin susceptibility against *S. aureus*[7]

Summary of vancomycin test result probabilities for predicting dalbavancin susceptibility at the FDA-approved breakpoint of ≤0.25 µg:

- *S. aureus* susceptibility >99.9% (n=33,688)

***In vitro* activity does not necessarily correlate with clinical results.**

IDEA study outline

IDEA (**I**nternational **D**albavancin **E**valuation of **A**ctivity) is an ongoing worldwide surveillance program that began in 2010.§ The IDEA 2019 US study surveyed the *in vitro* susceptibility activity of dalbavancin and vancomycin against Gram-positive bacteria such as *Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-susceptible *Staphylococcus aureus* (MSSA), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Enterococcus faecalis* (vancomycin-susceptible strains). A total of 10,646 bacterial isolates were collected from 31 medical centers in the United States and 37 medical centers in 19 European nations. The IDEA US study is funded by Allergan, Inc.[2]

†The FDA susceptible breakpoint for dalbavancin is ≤0.25 µg/mL.[5]

‡The CLSI susceptible breakpoint for vancomycin is ≤2 µg/mL.[8]

§Activity of dalbavancin has been monitored through the SENTRY Antimicrobial Surveillance Program since 2002.

CLSI, Clinical and Laboratory Standards Institute; FDA, Food and Drug Administration.

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.

Dalvance® (dalbavancin) for injection 500 mg

A long-acting agent with a proven safety and tolerability profile[5]

No known drug-drug interactions[5]

- 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

SELECTED ADVERSE REACTIONS IN ≥2% OF PATIENTS IN SINGLE-DOSE CLINICAL TRIAL*[5,9]

	DALVANCE SINGLE DOSE (N=349)	DALVANCE 2 DOSE (N=346)
Nausea	3.4%	2%

THE SAFETY PROFILE OF DALVANCE WAS EVALUATED ACROSS 8 PHASE 2 AND PHASE 3 TRIALS[5]

- The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%)[5]
- Serious adverse reactions occurred in 121/2473 (4.9%) of patients treated with any regimen of DALVANCE. In the Phase 2/3 trials comparing DALVANCE to comparator,† serious adverse reactions occurred in 109/1778 (6.1%) of patients in the DALVANCE group and 80/1224 (6.5%) of patients in the comparator group. In a Phase 3 trial comparing DALVANCE single-dose and 2-dose regimens, serious adverse reactions occurred in 7/349 (2.0%) of patients in the DALVANCE single-dose group and 5/346 (1.4%) of patients in the DALVANCE 2-dose group[5]
- DALVANCE was discontinued due to an adverse reaction in 64/2473 (2.6%) patients treated with any regimen of DALVANCE. In the Phase 2/3 trials comparing DALVANCE to comparator,† DALVANCE was discontinued due to an adverse reaction in 53/1778 (3.0%) of patients in the DALVANCE group and 35/1224 (2.9%) of patients in the comparator group. In a Phase 3 trial comparing DALVANCE single-dose and 2-dose regimens, DALVANCE was discontinued due to an adverse reaction in 6/349 (1.7%) of patients in the DALVANCE single-dose group and 5/346 (1.4%) of patients in the DALVANCE 2-dose group[5]
- *Clostridium difficile* colitis was reported in 0.2% of patients receiving DALVANCE in clinical trials[2]

*A causal relationship between study drug and adverse reactions was not always established.[5]
†Comparators included linezolid, cefazolin, cephalexin, and vancomycin.[5]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Infusion-related Reactions

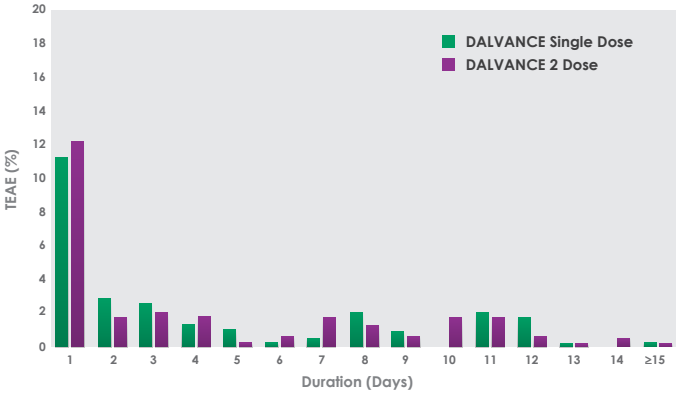
Rapid intravenous infusion of DALVANCE can cause reactions, including flushing of the upper body, urticaria, pruritus, rash, and/or back pain.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

In the single-dose DALVANCE trial...

Median duration of treatment-emergent adverse events (TEAE) was 3 days[2]

PERCENT OF TEAE‡ BY DAYS OF DURATION IN SINGLE-DOSE CLINICAL TRIAL



- The median duration of TEAE was 3.0 days in both treatment groups

‡TEAE included nausea, headache, vomiting, diarrhea, dizziness, cellulitis, chills, and localized infection.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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 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%).

Dalvance® (dalbavancin) for injection 500 mg

A single 1500 mg, 30-minute infusion provides a full course of therapy[5]

The Only SINGLE Dose — 30 Minute Infusion

NO RECOMMENDED DOSAGE ADJUSTMENT FOR MANY PATIENT POPULATIONS

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

- DALVANCE is also available as a 2-dose IV infusion: 1000 mg followed 1 week later by 500 mg

*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

Estimated CrCl	DALVANCE SINGLE DOSE	DALVANCE 2 DOSE
≥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.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

Helping patients with ABSSSI avoid the burden of daily IV treatment

No PICC line requirements[5]

- Patients receiving daily IV outpatient therapy may require a PICC line
- May avoid complications associated with PICC line insertion
- Average cost of each PICC line placement is $873[10]

No therapeutic drug monitoring required[5]

Low fluid volume[5]

- Minimum total fluid volume required for one 1500 mg infusion is 300 mL
- May be suitable for ABSSSI patients who also have fluid restrictions

Convenient storage and stability[5]

- Diluted intravenous solution may be stored either refrigerated or at a controlled room temperature for up to 48 hours; do not freeze

PICC, peripherally inserted central catheter.

Vial shown not actual size.

IMPORTANT SAFETY INFORMATION (continued)

Use in Specific Populations (continued)

- 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.

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.

Dalvance® (dalbavancin) for injection 500 mg

Dalvance Connects®—

Supporting patients with ABSSSI throughout their treatment

DALVANCE CONNECTS®

Visit DalvanceConnects.com, or call 1.855.387.2824

8 AM-8 PM ET, Monday-Friday, excluding holidays

Provides a comprehensive package of services including access to:

- Benefit verification
- Billing and coding support
- Prior authorization assistance
- Financial patient assistance, based on eligibility

The Dalvance Connects® Copay Assistance Program

Most patients* pay as little as $0

- The Dalvance Connects® Copay Assistance Program may assist eligible patients with their out-of-pocket costs for DALVANCE®, up to a maximum benefit of $2000 per calendar year

*Defined as at least 85% of commercial patient claims.

Expanded eligibility†

Any patient is eligible who:

- Is commercially insured
- Is a resident of, and is treated with DALVANCE in, the US
- Is administered DALVANCE in an outpatient care setting‡

†This is not insurance. Subject to change or discontinuation by AbbVie at any time.

‡Includes a practice-based or freestanding infusion center, hospital outpatient department, or home infusion service.

IMPORTANT SAFETY INFORMATION

Contraindications

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

Coding, coverage, and reimbursement

Payers typically reimburse hospitals for use of DALVANCE in the outpatient setting

DALVANCE is generally eligible for separate payment by Original Medicare, fee-for-service Medicaid, and most commercial health insurance plans when administered in the Emergency Department (ED) or in an outpatient setting of care.

Outpatient IV treatment can be administered in[11]:

- ED/observation unit
- Hospital-affiliated infusion centers
- Freestanding infusion centers
- Physician offices

A permanent J-code has been issued for DALVANCE

Code

J0875

Description:
Injection, dalbavancin, 5 mg

Billing Units:
Reported as 100 units for a single-use vial

NDC Number: 57970-100-01

Permanent J-codes may facilitate payment and simplify claims documentation and processing.

Vial shown not actual size.

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.

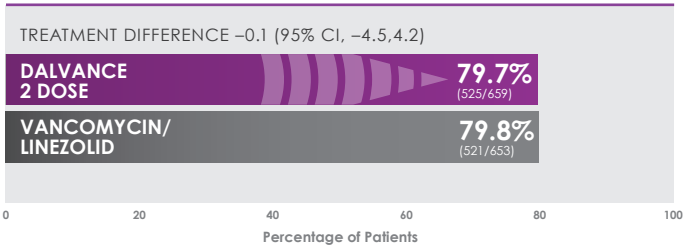
Dalvance® (dalbavancin) for injection 500 mg

In the DISCOVER trials...

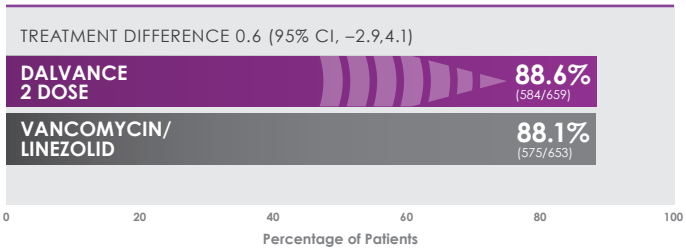
2-dose DALVANCE® provided early clinical response[1,2]

AT 48 TO 72 HOURS, 2-DOSE DALVANCE DEMONSTRATED RESPONSE RATES SIMILAR TO STANDARD OF CARE (POOLED ANALYSIS OF ITT POPULATION)*

Primary endpoint: cessation of lesion spread and absence of fever*



Key secondary endpoint: ≥20% reduction in lesion area†



- DALVANCE was shown to be noninferior to vancomycin/linezolid in these trials for the treatment of ABSSSI

Please see 2-dose study design on pages 20 and 21.

***Primary endpoint:** Clinical response rate where responders were defined as patients who had no increase from baseline in lesion area 48 to 72 hours after initiation of therapy and had a temperature consistently at or below 37.6°C upon repeated measurement.[5,12]

†**Secondary endpoint:** This key secondary endpoint evaluated the percentage of ITT patients achieving a 20% or greater reduction in lesion area from baseline at 48 to 72 hours after initiation of therapy.[5]

DISCOVER, **D**albavancin for **I**nfections of the **S**kin **CO**mpared to **V**ancomycin at an **E**arly **R**esponse.

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

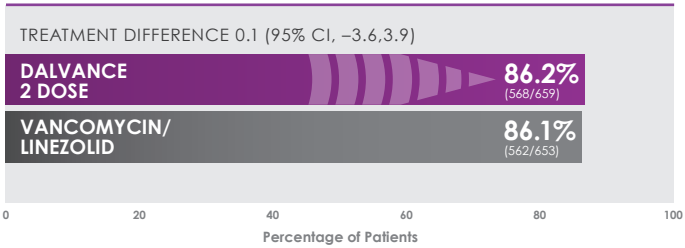
ALT elevations with DALVANCE treatment were reported in clinical trials.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

Proven clinical success at follow-up[2]

AT DAYS 26 TO 30, 2-DOSE DALVANCE DEMONSTRATED CLINICAL SUCCESS RATES SIMILAR TO STANDARD OF CARE (POOLED ANALYSIS OF ITT POPULATION)‡

Key secondary endpoint: decrease in lesion size, stable temperature, absent or mild and improved local signs‡



Comparisons of clinical success at follow-up cannot be used to establish noninferiority.§

‡**Secondary endpoint:** Another secondary endpoint was the clinical success rate assessed at a follow-up visit occurring between Days 26 to 30. Clinical success at this visit was defined as having a decrease in lesion size (both length and width measurements), a temperature of 37.6°C or lower, and meeting prespecified criteria for local signs: purulent discharge and drainage absent or mild and improved from baseline, heat/warmth and fluctuance absent, swelling/induration and tenderness to palpation absent or mild.[2]

§There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at the follow-up visit.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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

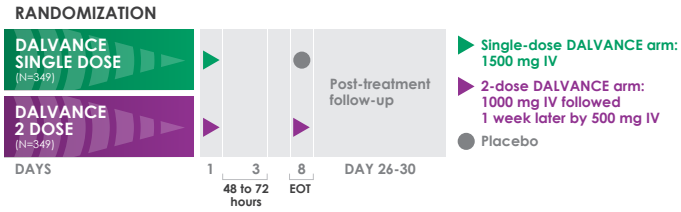
The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%).

Dalvance® (dalbavancin) for injection 500 mg

DALVANCE® single-dose study design[5,9]

Most study participants were treated as outpatients[9]

- Phase 3, randomized, double-blind, noninferiority trial evaluated the efficacy and safety of single-dose DALVANCE vs the 2-dose DALVANCE regimen[5,9]



- The ITT population included 698 randomized adult patients* with documented ABSSSI[5]
- Patient selection criteria: patients with cellulitis, abscess, or wound infection with a lesion size ≥75 cm^2 and at least 1 systemic sign of disease at baseline, defined as[9]:
  - Temperature ≥38°C,
  - WBC count >12,000 cells/mm^3, or
  - ≥10% band forms on WBC differential

*Patients with CrCl <30 mL/min had their dose adjusted. Approximately 5% of patients also received a protocol-specified empiric course of treatment with IV aztreonam for coverage of Gram-negative pathogens.[5]

CrCl, creatinine clearance; EOT, end of treatment; ITT, intent to treat; IV, intravenous; WBC, white blood cell.

Single-dose trial included a range of patients[9]

- In a total of 698 adult patients, a substantial portion had systemic signs of infection
- 54% of study participants were treated as outpatients and never admitted to the hospital

PATIENT CHARACTERISTICS AT BASELINE IN ITT POPULATION

SINGLE-DOSE vs 2-DOSE ABSSSI STUDY

	DALVANCE SINGLE DOSE (N=349)	DALVANCE 2 DOSE (N=349)
Area of infection, median (cm^2)	**296.1**	**293.3**
Type of infection % (n/N)		
Cellulitis	**47.9** (167/349)	**47.6** (166/349)
Major abscess	**24.6** (86/349)	**25.5** (89/349)
Traumatic wound/surgical site	**27.5** (96/349)	**26.9** (94/349)
Systemic signs of infection % (n/N)		
≥38°C (100.4°F)	**83.1** (290/349)	**81.8** (283/349)
(>12,000 cells/mm^3) WBC	**37.9** (132/349)	**36.8** (126/349)
(≥10%) Immature WBC forms (bands)	**21.3** (56/349)	**17.2** (46/349)
Current or former IV drug use % (n/N)	**30.1** (105/349)	**30.7** (107/349)
Hepatitis C % (n/N)	**14.0** (49/349)	**18.3** (64/349)
Body mass index, median	**26.9**	**27.8**
History of diabetes % (n/N)	**10.9** (38/349)	**12.0** (42/349)
Mean age (years)	**48.0**	**48.3**
Male gender % (n/N)	**58.5** (204/349)	**58.2** (203/349)

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

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).

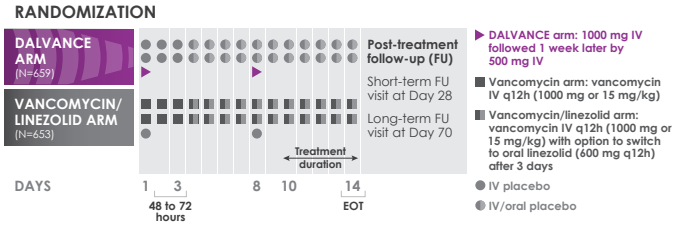
To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial agents, DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

Dalvance®
(dalbavancin) for injection
500 mg

DALVANCE® 2-dose study design[5,12]

ABSSSI DISCOVER trials included both inpatient and outpatient treatment[12]

- Two multicenter, randomized, double-blind, double-dummy, noninferiority trials of similar design with an active comparator (vancomycin/linezolid)[5,12]



DISCOVER, **D**albavancin for **I**nfections of the **S**kin **CO**mpared to **V**ancomycin at an **E**arly **R**esponse.

- The ITT population included 1312 randomized adult patients* with documented ABSSSI[5]
- Patient selection criteria: patients with cellulitis, abscess, or wound infection with a lesion size ≥75 cm^2 and at least 1 systemic sign of disease at baseline, defined as[5,12]:
  - Temperature ≥38°C (100.4°F),
  - Elevated WBC count (>12,000 cells/mm^3), or
  - 10% or more band forms on WBC differential

*Patients with CrCl <30 mL/min had their dose adjusted. Approximately 5% of patients also received a protocol-specified empiric course of treatment with IV aztreonam for coverage of Gram-negative pathogens.[5]

CrCl, creatinine clearance; EOT, end of treatment; ITT, intent to treat; IV, intravenous; q12h, every 12 hours; WBC, white blood cell.

IMPORTANT SAFETY INFORMATION

Contraindications

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

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, rash, and/or back pain.

Please see additional Important Safety Information throughout.
Please also see full Prescribing Information.

2-dose trial included a range of patients[12]

- In a total of 1312 adult patients, a substantial portion had systemic signs of infection
- 25% of study participants were treated as outpatients and never admitted to the hospital

POOLED PATIENT CHARACTERISTICS AT BASELINE IN ITT POPULATION

	2-DOSE DISCOVER TRIALS	
	DALVANCE 2 DOSE (N=659)	VANCOMYCIN/ LINEZOLID (N=653)
Area of infection, median (cm^2)	**324.0**	**367.0**
Type of infection % (n/N)		
Cellulitis	**53.7** (354/659)	**53.4** (349/653)
Major abscess	**24.6** (162/659)	**26.5** (173/653)
Traumatic wound/surgical site	**21.5** (142/659)	**20.1** (131/653)
Systemic signs of infection % (n/N)		
≥38°C (100.4°F)	**84.6** (549/649)	**85.0** (552/649)
(>12,000 cells/mm^3) WBC	**39.4** (247/627)	**40.3** (250/621)
(≥10%) Immature WBC forms (bands)	**23.2** (111/479)	**22.6** (108/478)
IV drug use % (n/N)	**14.3** (94/659)	**16.4** (107/653)
Body mass index, median	**N/A**	**N/A**
History of diabetes % (n/N)	**11.8** (78/659)	**14.1** (92/653)
Mean age (years)	**48.9**	**50.3**
Male gender % (n/N)	**59.6** (393/659)	**57.3** (374/653)

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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%).

Dalvance® (dalbavancin) for injection 500 mg

Inpatient care is an economic burden to hospital systems

Five days of inpatient treatment for ABSSSI can cost up to $11,501[2,10,13]

ILLUSTRATIVE COSTS ASSOCIATED WITH INPATIENT VANCOMYCIN TREATMENT*

		Vancomycin
Resource	**Cost per unit**	**5 days† inpatient[13]**
Hospital bed	$2090/day	$10,450
Vancomycin 1 g bid‡[2]	$12/day	$60
Therapeutic drug monitoring—renal function and trough levels	$118/blood draw	$118
PICC line placement§[10]	$873/placement	$873
Total		**$11,501**

***Illustrative costs do not include all costs associated with treatment of ABSSSI and do not represent overall cost of care.**

†Average LOS for ABSSSI patients.[13]

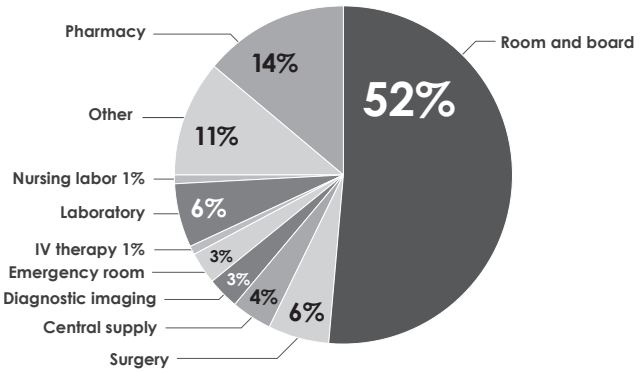
‡Cost of vancomycin updated November 2015.[2]

§Average cost per patient. Costs related to PICC-line complications may include physician visit, Cathflo® Activase® (alteplase) for declotting, declotting procedure, ER visits/rehospitalization for management, fluoroscopy for PICC placement, and PICC replacement. Cathflo® Activase® (alteplase) is a registered trademark of Genentech.[10]

bid, twice a day; ER, emergency room.

Over 50% of ABSSSI inpatient care costs were for room and board[2]

EXAMPLE OF ALLOCATION OF US COSTS BY DEPARTMENT FOR TREATING ABSSSI IN AN INPATIENT SETTING[2]



Hospital costs and utilization were evaluated using a national hospital database for 2010 covering 99,798 hospital discharges with the principal diagnosis of ABSSSI after exclusion criteria were applied. Diagnoses and procedures were categorized according to ICD-9 and CPT codes current at the time. Average LOS was 5 days. The most frequent initial antibiotic treatments included vancomycin, piperacillin/tazobactam, clindamycin, linezolid, daptomycin, and tigecycline.

Note: Numbers have been rounded to the nearest integer.

CPT, Current Procedural Terminology; ICD-9, International Classification of Diseases, 9th revision; IV, intravenous; LOS, length of stay.

References: 1. Pollack CV Jr, Amin A, Ford WT Jr, et al. Acute bacterial skin and skin structure infections (ABSSSI): practice guidelines for management and care transitions in the emergency department and hospital. *J Emerg Med*. 2015;48(4):508-519. doi:10.1016/j.jemermed.2014.12.001 **2.** Data on file. Allergan, Inc. **3.** Talan DA, Salhi BA, Moran GJ, et al. Factors associated with decision to hospitalize emergency department patients with skin and soft tissue infection. *West J Emerg Med*. 2015;16:89-97. **4.** Kaye KS, Petty LA, Shorr AF, Zilberberg MD. Current epidemiology, etiology, and burden of acute skin infections in the United States. *Clin Infect Dis*. 2019;68(suppl 3):S193-S199. **5.** DALVANCE® (dalbavancin) [prescribing information]. Madison, NJ: Allergan USA, Inc.; 2018. **6.** Carrothers TJ, Chittenden JT, Critchley I. Dalbavancin population pharmacokinetic modeling and target attainment analysis. *Clin Pharmacol Drug Dev*. 2020;9(1):21-31. doi:10.1002/cpdd.695 **7.** Jones RN, Farrell DJ, Flamm RK, et al. Surrogate analysis of vancomycin to predict susceptible categorization of dalbavancin. *Diagn Microbiol Infect Dis*. 2015;82(1):73-77. doi:10.1016/j.diagmicrobio.2015.01.017 **8.** Clinical and Laboratory Standards Institute. *Performance Standards for Antimicrobial Susceptibility Testing*. 27th ed. CLSI supplement M100S. Wayne, PA: Clinical and Laboratory Standards Institute; 2017. **9.** 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. doi:10.1093/cid/civ982 **10.** Ektare V, Khachatryan A, Xue M, Dunne M, Johnson K, Stephens J. Assessing the economic value of avoiding hospital admissions by shifting the management of gram+ acute bacterial skin and skin-structure infections to an outpatient care setting. *J Med Econ*. 2015;18(12):1092-1101. doi:10.3111/13696998.2015.1078339 **11.** Tice AD, Rehm SJ, Dalovisio JR, et al. Practice guidelines for outpatient parenteral antimicrobial therapy. IDSA guidelines. *Clin Infect Dis*. 2004;38(12):1651-1672. doi:10.1086/420939 **12.** Boucher HW, Wilcox M, Talbot GH, Puttagunta S, Das AF, Dunne MW. Once-weekly dalbavancin versus daily conventional therapy for skin infection. *N Engl J Med*. 2014;370(23):2169-2179. doi:10.1056/NEJMoa1310480 **13.** Kaye KS, Patel DA, Stephens JM, Khachatryan A, Patel A, Johnson K. Rising United States hospital admissions for acute bacterial skin and skin structure infections: recent trends and economic impact. *PLoS One*. 2015;10(11):e0143276. doi:10.1371/journal.pone.0143276

Reducing exposure to the healthcare system for patients with ABSSSI

Dalvance®

Change the Treatment Journey

- **A single 30-minute infusion of DALVANCE provided early clinical response and clinical success at follow-up[5]**
- **A long-acting agent with no known drug-drug interactions and a proven safety and tolerability profile[5]**
- **No PICC lines or therapeutic drug monitoring required[5]**
- **Comprehensive outpatient reimbursement and financial support via Dalvance Connects®**

The Only SINGLE Dose

30 Minute Infusion

INDICATION AND USAGE

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abbvie

Dalvance® (dalbavancin) for injection 500 mg