Department of Health and Human Services
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Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Epidemiology

Pediatric Postmarketing Pharmacovigilance Review

Date:	November 7, 2025
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Product Name:	Dalvance (dalbavancin)
Pediatric Labeling Approval Date:	July 22, 2021
Application Type/Number:	NDA 021883
Applicant:	AbbVie, Inc.
TTT Record ID:	2025-16532

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Dalvance (dalbavancin) in pediatric patients less than 18 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Pediatric Research Equity Act (PREA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with dalbavancin in pediatric patients.

Dalvance (dalbavancin) is a lipoglycopeptide antibacterial, initially approved in the U.S. on May 23, 2014. Dalbavancin is currently indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms.

This pediatric postmarketing safety review was prompted by pediatric labeling approved on July 22, 2021, that expanded the use of dalbavancin for the treatment of ABSSSI to include pediatric patients from birth to less than 18 years. Data to support use in this population is included in the *Pediatric Use* subsection of labeling (see **Section 1.2**). Dalbavancin has not been previously presented before the Pediatric Advisory Committee.

DPV searched FAERS for all U.S. serious reports with dalbavancin in pediatric patients less than 18 years of age from July 22, 2020, through September 18, 2025, and did not identify any reports.

DPV did not identify any new pediatric safety concerns for dalbavancin at this time and will continue routine pharmacovigilance monitoring for dalbavancin.

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Dalvance (dalbavancin) in pediatric patients less than 18 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Pediatric Research Equity Act (PREA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with dalbavancin in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Dalvance (dalbavancin) is a lipoglycopeptide antibacterial and was initially approved in the U.S. on May 23, 2014.[1] Dalbavancin is currently indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms.[2]

This pediatric postmarketing safety review was prompted by pediatric labeling approved on July 22, 2021, that expanded the use of dalbavancin for the treatment of ABSSSI to include pediatric patients from birth to less than 18 years.[3] Data to support use in this population is included in the *Pediatric Use* subsection of labeling (see **Section 1.2**). Dalbavancin has not been previously presented before the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION

The dalbavancin labeling contains the following safety information excerpted from the Highlights of Prescribing Information and the *Pediatric Use* subsection. For additional dalbavancin labeling information, please refer to the full prescribing information.[2]

CONTRAINDICATIONS

Known hypersensitivity to dalbavancin (*4*)

WARNINGS AND PRECAUTIONS

- Serious hypersensitivity (anaphylactic) and skin reactions have been reported in patients treated with DALVANCE. If an allergic reaction occurs, discontinue treatment with DALVANCE and institute appropriate therapy for the allergic reaction. Carefully monitor patients with known hypersensitivity to glycopeptides. (*5.1*)
- Rapid intravenous infusion of DALVANCE can cause flushing of the upper body, urticaria, pruritus, rash, and/or back pain. Stopping or slowing the infusion may result in cessation of these reactions. (*5.2*)
- Alanine Aminotransferase (ALT) elevations with DALVANCE treatment were reported in clinical trials. (*5.3, 6.1*)
- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE. Evaluate if diarrhea occurs. (*5.4*)

ADVERSE REACTIONS

The most common adverse reactions occurring in >4% of adult patients treated with DALVANCE were nausea, headache, and diarrhea. The most common adverse reaction that occurred in >1% of pediatric patients was pyrexia. (*6.1*)

8.4 Pediatric Use

The safety and effectiveness of DALVANCE for the treatment of ABSSSI has been established in pediatric patients aged birth to less than 18 years. Use of DALVANCE for this indication is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients aged birth to less than 18 years *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14.1)]*.

There is insufficient information to recommend dosage adjustment for pediatric patients with ABSSSI and CLcr less than 30 mL/min/1.73m^2 *[see Dosage and Administration (2.2)]*.

2 METHODS AND MATERIALS

2.1 FAERS SEARCH STRATEGY

DPV searched the FAERS database with the strategy described in **Table 1**.

Table 1. FAERS Search Strategy*

Date of search	September 19, 2025
Time period of search	July 22, 2020† - September 18, 2025
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	PAI: Dalbavancin, dalbavancin hydrochloride
MedDRA search terms (Version 28.0)	All Preferred Terms
Other criteria	Case Seriousness: Serious‡ Country Derived: USA

* See **Appendix A** for a description of the FAERS database.
† The Division of Anti-Infectives/Office of Infectious Diseases multidisciplinary review for NDA 021883/S-010 completed in July 2021 included a search of the FAERS database for pediatric patients. The review did not identify any new signals. For completeness, the data lock date for the FAERS search for this review is one year prior to the pediatric labeling date.
‡ For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention, or other serious important medical events.
Abbreviations: PAI=Product Active Ingredient, MedDRA=Medical Dictionary for Regulatory Activities, USA=United States of America

3 RESULTS

3.1 FAERS

3.1.1 Selection of U.S. Serious Pediatric Cases in FAERS

Our FAERS search retrieved no U.S. serious pediatric reports for patients less than 18 years old from July 22, 2020, through September 18, 2025.

3.1.2 Summary of U.S. Fatal Pediatric Cases (N=0)

There are no fatal pediatric adverse event cases for discussion.

3.1.3 Summary of U.S. Serious Non-Fatal Pediatric Cases (N=0)

There are no non-fatal pediatric adverse event cases for discussion.

4 DISCUSSION

DPV searched FAERS for all U.S. serious reports with dalbavancin in pediatric patients less than 18 years of age from July 22, 2020, through September 18, 2025, and did not identify any reports.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with dalbavancin in pediatric patients less than 18 years of age.

5 CONCLUSION

DPV did not identify any new pediatric safety concerns for dalbavancin at this time and will continue routine pharmacovigilance monitoring for dalbavancin.

6 REFERENCES

[1] Dalvance (dalbavancin)[package insert]. Chicago, IL: Durata Therapeutics U.S. Limited. May 23, 2014. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021883s000lbl.pdf. Accessed on September 23, 2025.
[2] Dalvance (dalbavancin)[package insert]. North Chicago, IL: AbbVie Inc. Revised January 13, 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/021883Orig1s012lbl.pdf. Accessed on September 23, 2025.
[3] Dalvance (dalbavancin)[package insert]. Madison, NJ: Allergan USA, Inc. Revised July 22, 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021883s010lbl.pdf. Accessed on September 23, 2025.

7 APPENDICES

7.1 APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support FDA's postmarketing safety surveillance program for drug and therapeutic biological products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Council on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary.

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.