Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Epidemiology

Pediatric Postmarketing Pharmacovigilance Review

Date:	May 28, 2026
Reviewers:	Kate McCartan, MD, Medical Officer Division of Pharmacovigilance II
	Ivone Kim, MD, Medical Officer Division of Pharmacovigilance I
Team Leader:	Rachna Kapoor, PharmD, MBA Division of Pharmacovigilance II
Deputy Division Director:	Sara Camilli, PharmD, BCPS Division of Pharmacovigilance II
Product Name:	Zevtera (ceftobiprole medocaril sodium)
Pediatric Labeling Approval Date:	April 3, 2024
Application Type/Number:	NDA 218275
Applicant:	ISTx, LLC
TTT Record ID:	2026-20294

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Zevtera (ceftobiprole medocaril sodium) 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 ceftobiprole in pediatric patients.

Zevtera (ceftobiprole medocaril sodium) is a cephalosporin antibacterial and was FDA approved on April 3, 2024. Ceftobiprole is indicated for the treatment of: adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis; adult patients with acute bacterial skin and skin structure infections; and adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia.

This pediatric postmarketing safety review was prompted by pediatric labeling at approval for the indication of treatment of community-acquired bacterial pneumonia in pediatric patients aged 3 months to 18 years.

DPV searched FAERS for all U.S. serious reports with ceftobiprole in pediatric patients less than 18 years of age from April 3, 2024, through April 7, 2026, and did not identify any reports.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Zevtera (ceftobiprole medocaril sodium) 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 ceftobiprole in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Zevtera (ceftobiprole medocaril sodium) is a cephalosporin antibacterial and was FDA approved on April 3, 2024.[1] Ceftobiprole is indicated for the treatment of: adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis; adult patients with acute bacterial skin and skin structure infections; and adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia.

This pediatric postmarketing safety review was prompted by pediatric labeling at approval for the indication of treatment of community-acquired bacterial pneumonia in pediatric patients aged 3 months to 18 years. Data to support use for this indication in this population is included in the Pediatric Use subsection of labeling (see **Section 1.2**).

1.2 RELEVANT LABELED SAFETY INFORMATION

The ceftobiprole labeling contains the following safety information excerpted from the Highlights of Prescribing Information and the *Pediatric Use* subsection. For additional ceftobiprole labeling information, please refer to the full prescribing information.[1]

----------CONTRAINDICATIONS----------

ZEVTERA is contraindicated in patients with a known history of severe hypersensitivity to ZEVTERA, or to other members of the cephalosporin class (4).

----------WARNINGS AND PRECAUTIONS----------

- Increased Mortality with Unapproved use in Ventilator-Associated Bacterial Pneumonia (VABP) Patients: The safety and effectiveness of ZEVTERA for the treatment of VABP has not been established and the use of ZEVTERA for VABP is not approved (5.1).
- Hypersensitivity Reactions: Discontinue ZEVTERA if a hypersensitivity reaction occurs, and institute appropriate treatment (5.2).
- Seizures and other adverse central nervous system (CNS) reactions have been associated with the use of ZEVTERA. If seizures or other CNS adverse reactions occur, evaluate patients to determine whether ZEVTERA should be discontinued (5.3).
- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including ZEVTERA. Evaluate if diarrhea occurs (5.4).

----------ADVERSE REACTIONS----------

- SAB (adult patients): The most common adverse reactions occurring in ≥ 4% of adult patients were anemia, nausea, hypokalemia, vomiting, hepatic enzyme and bilirubin increased, diarrhea, blood creatinine increased, hypertension, leukopenia, and pyrexia (6.1).
- ABSSSI (adult patients): The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, diarrhea, headache, injection site reaction, hepatic enzyme increased, rash, vomiting, and dysgeusia (6.1).
- CABP (adult and pediatric patients 3 months to less than 18 years of age):
    - Adult Patients: The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, hepatic enzyme increased, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, hypertension, and dizziness (6.1).
    - Pediatric Patients: The most common adverse reactions occurring in ≥ 2% of pediatric patients were vomiting, headache, hepatic enzyme increased, diarrhea, infusion site reaction, phlebitis and pyrexia (6.1).

8.4 Pediatric Use

The safety and effectiveness of ZEVTERA have been established for the treatment of CABP in pediatric patients 3 months to less than 18 years. Use of ZEVTERA in this age group is supported by evidence from an adequate and well-controlled trial of ZEVTERA in adults, with additional pharmacokinetic, safety and efficacy data from pediatric trials [see Adverse Reactions (6.1), Clinical Pharmacology (12.3), Clinical Studies (14.3)].

The safety and effectiveness of ZEVTERA have not been established for the treatment of CABP in pediatric patients less than 3 months of age.

The safety and effectiveness of ZEVTERA have not been established for the treatment of ABSSSI and SAB in pediatric patients.

2 METHODS AND MATERIALS

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

Table 1. FAERS Search Strategy*

Date of search	April 8, 2026
Time period of search	April 3, 2024† - April 7, 2026
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	PAI: Ceftobiprole, ceftobiprole medocaril, ceftobiprole medocaril sodium
MedDRA search terms (Version 28.1)	All Preferred Terms

* See **Appendix A** for a description of the FAERS database.
† U.S. approval date.
Abbreviation: PAI=Product Active Ingredient, MedDRA=Medical Dictionary for Regulatory Activities

3 RESULTS

3.1 SELECTION OF U.S. SERIOUS PEDIATRIC CASES IN FAERS

Our FAERS search retrieved no U.S. serious[a] pediatric reports for patients less than 18 years old from April 3, 2024, through April 7, 2026.

3.2 SUMMARY OF U.S. FATAL PEDIATRIC CASES (N=0)

There are no fatal pediatric adverse event cases for discussion.

3.3 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 ceftobiprole in pediatric patients less than 18 years of age from April 3, 2024, through April 7, 2026, 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 ceftobiprole in pediatric patients less than 18 years of age.

5 CONCLUSION

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

[a] 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.

6 REFERENCES

[1] Zevtera (ceftobiprole medocaril sodium)[package insert]. Odate-Shi, Akita, Japan: Nipro Pharma Corporation. April 3, 2024. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf. Accessed April 10, 2026.

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 is consistent with international safety reporting guidance issued by the International Council on Harmonisation and adheres to FDA guidance on adverse event reporting. 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.