Department of Health and Human Services
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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:	April 20, 2026
Reviewers:	Omayma Kishk, PharmD, BCPPS, Safety Evaluator Division of Pharmacovigilance I (DPV-I) Ivone Kim, MD, Medical Officer DPV-I
Team Leader:	Carmen Cheng, PharmD DPV-I
Division Director:	Monica Muñoz, PharmD, PhD, BCPS DPV-I
Product Name:	Zelsuvmi (berdazimer sodium) topical gel
Pediatric Labeling Approval Date:	January 5, 2024
Application Type/Number:	NDA 217424
Applicant:	LNHC, Inc.
TTT Record ID:	2026-18610

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EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Zelsuvmi (berdazimer sodium) topical gel 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 berdazimer sodium in pediatric patients.

Zelsuvmi (berdazimer sodium) topical gel is a nitric oxide releasing agent that was initially FDA approved on January 5, 2024. Berdazimer sodium is currently indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

This pediatric postmarketing safety review was prompted by the pediatric labeling on January 5, 2024, that established the safety and effectiveness of berdazimer sodium for the topical treatment of MC in pediatric patients 1 year of age and older. The safety and effectiveness of berdazimer sodium have not been established in pediatric patients younger than 1 year of age.

A pediatric safety review for berdazimer sodium has not previously been presented to the Pediatric Advisory Committee.

DPV searched FAERS for all U.S. serious reports with berdazimer sodium in pediatric patients less than 18 years of age from January 5, 2024, through January 26, 2026, and identified no reports.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Zelsuvmi (berdazimer sodium) topical gel 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 berdazimer sodium in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Zelsuvmi (berdazimer sodium) topical gel is a nitric oxide releasing agent that was initially FDA approved on January 5, 2024. Berdazimer sodium is currently indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.[1]

This pediatric postmarketing safety review was prompted by the pediatric labeling on January 5, 2024, that established the safety and effectiveness of berdazimer sodium for the topical treatment of MC in pediatric patients 1 year of age and older. The safety and effectiveness of berdazimer sodium have not been established in pediatric patients younger than 1 year of age.

A pediatric safety review for berdazimer sodium has not previously been presented to the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION

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

----------CONTRAINDICATIONS----------
None.(4)

----------WARNINGS AND PRECAUTIONS----------
Application Site Reactions: Application site reactions, including allergic contact dermatitis, occurred. Discontinue ZELSUVMI and initiate appropriate therapy. (5.1)

----------ADVERSE REACTIONS----------
The most commonly reported adverse reactions (≥1%) are application site reactions, including pain (such as burning or stinging sensations, 18.7%), erythema (11.7%), pruritus (5.7%), exfoliation (5.0%), dermatitis (4.9%), swelling (3.5%), erosion (1.6%), discoloration (1.5%), vesicles (1.5%), irritation (1.2%), and infection (1.1%). (6.1)

8.4 Pediatric Use
The safety and effectiveness of ZELSUVMI for the topical treatment of MC have been established in pediatric patients 1 year of age and older. Use of ZELSUVMI for this indication is supported by data from three randomized, vehicle-controlled, double-blind trials involving 1596 subjects of which 1575 were pediatric subjects with MC (904 were exposed to ZELSUVMI; 29 subjects were less than 2 years of age, including one subject less than 1 year of age, and 875 were 2 to 17 years of age) *[see Clinical Studies (14)].*

The safety and effectiveness of ZELSUVMI have not been established in pediatric patients younger than 1 year of age.

2 METHODS AND MATERIALS

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

Table 1. FAERS Search Strategy[*]

Date of search	January 27, 2026
Time period of search	January 5, 2024[†] - January 26, 2026
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product term	Product active ingredient: Berdazimer 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: MedDRA=Medical Dictionary for Regulatory Activities

3 RESULTS

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

Our FAERS search retrieved zero U.S. serious[a] pediatric reports from January 5, 2024, through January 26, 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 berdazimer sodium in pediatric patients less than 18 years of age from January 5, 2024, through January 26, 2026, and identified no reports.

5 CONCLUSION

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

[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. Zelsuvmi® (berdazimer) topical gel [Prescribing Information]. Wilmington, Delaware: EPIH SPV, LLC; January 2024.

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.