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 7, 2025
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Product Name:	Ycanth (cantharidin) topical solution
Pediatric Labeling Approval Date:	July 21, 2023
Application Type/Number:	NDA 212905
Applicant:	Verrica Pharmaceuticals, Inc
TTT Record ID:	2025-13766

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EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Ycanth (cantharidin) Topical Solution in pediatric patients less than 17 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 cantharidin in pediatric patients.

Ycanth (cantharidin) topical solution is a vesicant initially approved in the U.S. on July 21, 2023. Cantharidin is currently indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

This pediatric postmarketing safety review was stimulated by pediatric labeling on July 21, 2023, that approved cantharidin for the topical treatment of molluscum contagiosum in pediatric patients 2 years of age and older.

DPV reviewed all U.S. serious FAERS reports with cantharidin in pediatric patients less than 17 years of age from July 21, 2023, through March 17, 2025, and identified one report; however, this report was excluded from further discussion.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with cantharidin in pediatric patients less than 17 years of age.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Ycanth (cantharidin) topical solution in pediatric patients less than 17 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 cantharidin in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY[1]

Ycanth (cantharidin) topical solution is a vesicant initially approved in the U.S. on July 21, 2023. Cantharidin is currently indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

This pediatric postmarketing safety review was stimulated by pediatric labeling on July 21, 2023, that approved cantharidin for the topical treatment of molluscum contagiosum in pediatric patients 2 years of age and older.

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

1.2 RELEVANT LABELED SAFETY INFORMATION[2]

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

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

- None.

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

- Toxicities Associated with Inappropriate Administration: Life threatening or fatal toxicities can occur if administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if YCANTH comes in contact with eyes. If YCANTH gets in eyes, flush eyes with water for at least 15 minutes.
- Local Skin Reactions: Reactions at the application site have included vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin. If YCANTH contacts any unintended surface, or healthy skin, immediately remove. If severe local skin reactions occur, remove prior to 24 hours after treatment.
- Flammability: YCANTH is flammable, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.

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

- Most common (incidence ≥1%) adverse reactions are the following local skin reactions at the application site: vesiculation, pain, pruritus, scabbing, erythema, discoloration, application site dryness, edema, and erosion.

----------USE IN SPECIFIC POPULATIONS----------

8.4 Pediatric Use

Risk Summary The safety and effectiveness of YCANTH for the treatment of molluscum contagiosum have been established in pediatric patients aged 2 years and older. The use of YCANTH in pediatric patients is supported by results from adequate and well-controlled trials in patients 2 years of age and older; although the safety and efficacy of drug use for longer than 12 weeks has not been established.

The safety and efficacy in pediatric patients below the age of 2 years have not been established.

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	March 18, 2025
Time period of search	July 21, 2023† - March 17, 2025
Search type	RxLogix Pediatric Focused Review Alert
Product terms	Product Active Ingredient: cantharidin
MedDRA search terms (Version 27.1)	All Preferred Terms
Other search terms‡	Case Seriousness: Serious Country Derived: USA
* See Appendix A for a description of the FAERS database. † U.S. approval date for Ycanth (cantharidin) ‡ 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: 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 one U.S. serious pediatric report for patients less than 17 years old from July 21, 2023, through March 17, 2025. We excluded this report because it does not contain sufficient information to assess causality.

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 reviewed all U.S. serious FAERS reports with cantharidin in pediatric patients less than 17 years of age from July 21, 2023, through March 17, 2025, and identified one report; however, this report was excluded from further discussion.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with cantharidin in pediatric patients less than 17 years of age.

5 CONCLUSION

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

6 REFERENCES

1. Approval letter. NDA 212905. July 21, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/212905Orig1s000ltr.pdf Accessed: March 21, 2025

2. Ycanth (cantharidin) [package insert]. West Chester, PA. Verrica Pharmaceuticals, Inc. July 2023.

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.