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:	June 6, 2025
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Product Name:	Solosec (secnidazole)
Pediatric Labeling Approval Date:	January 26, 2022
Application Type/Number:	NDA 209363
Applicant:	Evofem Inc.
TTT Record ID:	2025-14291

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EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Solosec (secnidazole) 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 secnidazole in pediatric patients.

Solosec (secnidazole) is a nitroimidazole antimicrobial, initially approved in the U.S. on September 15, 2017. Secnidazole is currently indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older and the treatment of trichomoniasis in patients 12 years of age and older.

This pediatric postmarketing safety review was prompted by pediatric labeling on January 26, 2022, that expanded the patient population to include the treatment of bacterial vaginosis in female patients 12 years of age and older and the treatment of trichomoniasis in patients 12 years of age and older. Data to support use in this population is included in the *Pediatric Use* subsection of labeling (see **Section 1.2**).

DPV searched FAERS for all U.S. serious reports with secnidazole in pediatric patients less than 18 years of age from September 15, 2017, through April 22, 2025, and did not identify any reports.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Solosec (secnidazole) 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 secnidazole in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Solosec (secnidazole) is a nitroimidazole antimicrobial and was initially approved in the U.S. on September 15, 2017.[1] Secnidazole is currently indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older and for the treatment of trichomoniasis in patients 12 years of age and older.[2]

This pediatric postmarketing safety review was prompted by pediatric labeling on January 26, 2022, that expanded the patient population to include the treatment of bacterial vaginosis in female patients 12 years of age and older and the treatment of trichomoniasis in patients 12 years of age and older. Data to support use in this population is included in the *Pediatric Use* subsection of labeling (see **Section 1.2**).

1.2 RELEVANT LABELED SAFETY INFORMATION

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

..... CONTRAINDICATIONS .....

- History of hypersensitivity to secnidazole, or other nitroimidazole derivatives. (4)
- Patients with Cockayne syndrome. (4, 6.2)

..... WARNING AND PRECAUTIONS .....

- Vulvovaginal Candidiasis: This may develop with SOLOSEC and require treatment with an antifungal agent. (5.1)
- Potential Risk for Carcinogenicity: Carcinogenicity has been seen in mice and rats treated chronically with nitroimidazole derivatives, which are structurally related to secnidazole. It is unclear if the positive tumor findings in lifetime rodent studies indicate a risk to patients taking a single dose of SOLOSEC to treat bacterial vaginosis. Avoid chronic use. (5.2)

..... ADVERSE REACTIONS .....

- Bacterial Vaginosis: Most common adverse reactions observed in clinical trials of bacterial vaginosis (incidence ≥ 2%) were vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus. (6.1).
- Trichomoniasis: Most common adverse reaction observed in the clinical trial of trichomoniasis (incidence ≥ 2%) was vulvovaginal candidiasis. (6.1).

8.4 Pediatric Use

The safety and effectiveness of SOLOSEC for the treatment of bacterial vaginosis have been established in pediatric patients aged 12 to 17 years old. Use of SOLOSEC in this age group is supported by evidence from a multicenter, open-label safety study in 40 pediatric female patients with bacterial vaginosis [see Adverse Reactions (6.1)] and evidence from adequate and well-controlled studies in adult women [see Clinical Studies (14.1)].

The safety and effectiveness of SOLOSEC for the treatment of trichomoniasis have been established in pediatric patients aged 12 to 17 years old. Use of SOLOSEC in this group is based on the extrapolation of clinical trial data from adult women with trichomoniasis, four open-label trials in males with trichomoniasis, and an open-label safety study in pediatric female patients with bacterial vaginosis [see Adverse Reactions (6.1) and Clinical Studies (14.2)]. The safety and effectiveness of SOLOSEC in pediatric patients below the age of 12 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	April 23, 2025
Time period of search	September 15, 2017† - April 22, 2025
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	Product Active Ingredient: Secnidazole
MedDRA search terms (Version 27.1)	All Preferred Terms
Other criteria	Case Seriousness: Serious‡ Country Derived: USA
* See **Appendix A** for a description of the FAERS database. † U.S. approval 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: 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 September 15, 2017, through April 22, 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 secnidazole in pediatric patients less than 18 years of age from September 15, 2017, through April 22, 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 secnidazole in pediatric patients less than 18 years of age.

5 CONCLUSION

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

6 REFERENCES

[1] Solosec (secnidazole)[package insert]. Somerset, NJ: Catalent Pharma Solutions. September 15, 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209363s000lbl.pdf. Accessed April 24, 2025.

[2] Solosec (secnidazole)[package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc. January 26, 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209363Orig1s014s016lbl.pdf. Accessed April 24, 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.