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:	March 18, 2025
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Product Name:	Cosentyx (secukinumab) injection
Pediatric Labeling Approval Date:	May 28, 2021
Application Type/Number:	BLA 125504
Applicant:	Novartis Pharmaceuticals Corporation
TTT Record ID:	2025-12956

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EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Cosentyx (secukinumab) injection 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 secukinumab in pediatric patients.

Cosentyx (secukinumab) injection is a human interleukin-17A antagonist initially approved in the U.S. on January 21, 2015, as an injection for subcutaneous use (BLA 125504). On October 6, 2023, FDA approved Cosentyx injection for intravenous use (BLA 761349). Cosentyx is currently indicated for the treatment of:

- moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
- active psoriatic arthritis (PsA) in patients 2 years of age and older
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older
- adults with moderate to severe hidradenitis suppurativa (HS)

This pediatric postmarketing safety review was prompted by pediatric labeling on May 28, 2021, that expanded the secukinumab indication to include use in the treatment of PsO in pediatric patients aged 6 years and older.

DPV has not previously performed a pediatric postmarketing pharmacovigilance review for secukinumab for the Pediatric Advisory Committee.

DPV reviewed all U.S. serious FAERS reports with secukinumab in pediatric patients less than 17 years of age from January 21, 2015 – January 29, 2025, and identified 25 reports; however, all reports were 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 secukinumab in pediatric patients less than 17 years of age.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Cosentyx (secukinumab) injection 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 secukinumab in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Cosentyx (secukinumab) is a human interleukin-17A antagonist initially approved in the U.S. on January 21, 2015, as an injection for subcutaneous use (BLA 125504).[1] On October 6, 2023, FDA approved Cosentyx injection for intravenous use (BLA 761349).[2] Cosentyx is currently indicated for the treatment of:[3]

- moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
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This pediatric postmarketing safety review was prompted by pediatric labeling on May 28, 2021, that expanded the secukinumab indication to include use in the treatment of PsO in pediatric patients aged 6 years and older.[4]

DPV has not previously performed a pediatric postmarketing pharmacovigilance review for secukinumab for the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION

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

> ----------CONTRAINDICATIONS----------
> Serious hypersensitivity to secukinumab or any excipients in COSENTYX. (4)
>
> ----------WARNINGS AND PRECAUTIONS----------
> - Infections: Serious infections, have occurred. Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. If a serious infection develops, discontinue COSENTYX until the infection resolves. (5.1)
> - Hypersensitivity Reactions: If an anaphylactic reaction or other serious allergic reaction occurs, discontinue COSENTYX immediately and initiate appropriate therapy. (5.2)
> - Tuberculosis (TB): Prior to initiating treatment with COSENTYX, evaluate for TB. (5.3)
> - Inflammatory Bowel Disease (IBD): Cases of IBD were observed in clinical trials. Exercise caution when prescribing COSENTYX to patients with IBD. (5.4)
> - Eczematous Eruptions: Cases of severe eczematous eruptions have occurred in patients receiving COSENTYX. (5.5)
> - Immunizations: Avoid use of live vaccines in patients treated with COSENTYX. (5.7)

----------ADVERSE REACTIONS----------
Most common adverse reactions (> 1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection. (6.1)

8.4 Pediatric Use
Subcutaneous Administration
Pediatric Plaque Psoriasis
The safety and effectiveness of COSENTYX have been established for the treatment of moderate to severe PsO in pediatric patients aged 6 years and older who are candidates for systemic therapy or phototherapy [see Adverse Reactions (6.1) and Clinical Studies (14.2)].

Safety and effectiveness of COSENTYX in pediatric patients with PsO below the age of 6 years have not been established.

Juvenile Psoriatic Arthritis (JPsA)
The safety and effectiveness of COSENTYX have been established for the treatment of active JPsA in pediatric patients aged 2 years and older who weigh 15 kg or more [see Adverse Reactions (6.1) and Clinical Studies (14.6)].

The safety and effectiveness of COSENTYX in pediatric patients less than 2 years of age with JPsA or with a body weight less than 15 kg has not been established.

Enthesitis-Related Arthritis
The safety and effectiveness of COSENTYX for the treatment of active ERA in pediatric patients aged 4 years and older who weigh 15 kg or more has been established [see Adverse Reactions (6.1) and Clinical Studies (14.6)].

The safety and effectiveness of COSENTYX in pediatric patients below the age of 4 years old or with body weight less than 15 kg have not been established.

Hidradenitis Suppurativa
The safety and effectiveness of COSENTYX in pediatric patients with HS have not been established.

Intravenous Administration
The safety and effectiveness of intravenous COSENTYX in pediatric patients 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	January 30, 2025
Time period of search	January 21, 2015† - January 29, 2025
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	Product active ingredient: Secukinumab
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.
† Cosentyx 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

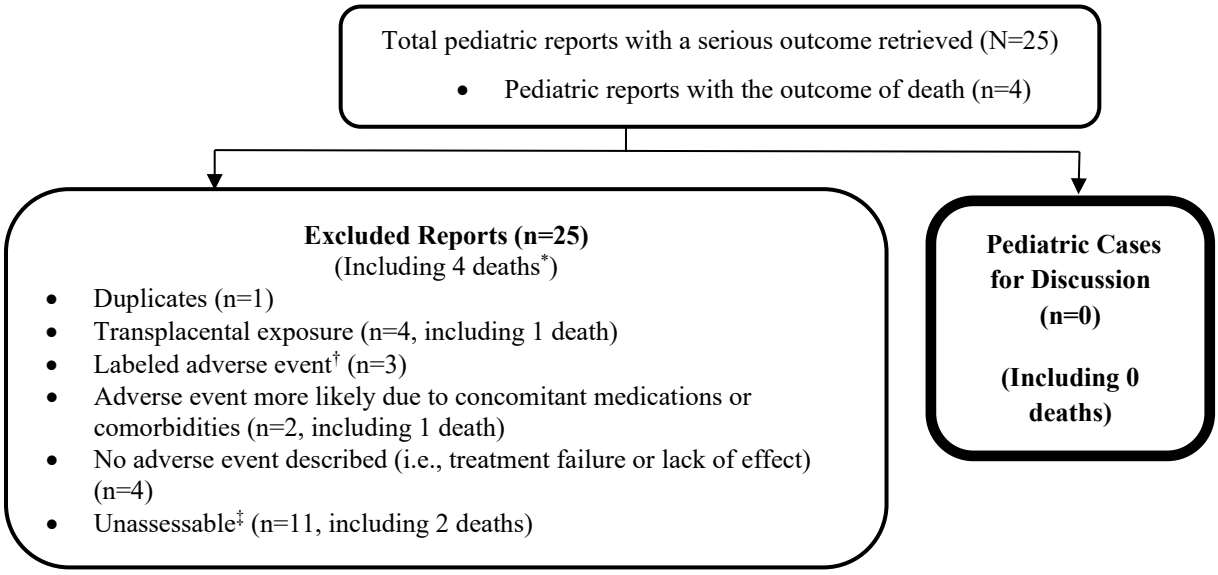
3 RESULTS

3.1 FAERS

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

Our FAERS search retrieved 25 U.S. serious pediatric reports for patients less than 17 years old from January 21, 2015 – January 29, 2025.[1] We reviewed all U.S. FAERS pediatric reports with a serious outcome. We excluded all 25 reports from the case series for the reasons listed in **Figure 1**. **Figure 1** presents the selection of cases for the pediatric case series.

Figure 1. Selection of U.S. Serious Pediatric Cases With Secukinumab



* Four excluded U.S. FAERS reports described fatal outcomes. None of the deaths were determined to be attributed to secukinumab. One case described a neonate with prenatal exposure to secukinumab who died due to complications from an unspecified congenital heart defect. One case described a neonate who received secukinumab for the treatment of congenital ichthyosis and later died from multisystem organ failure as a consequence of underlying congenital renal disease and heart defects. Two cases contained no clinical information to understand the clinical events or perform a causality assessment for secukinumab.
† Labeled adverse event does not represent increased severity.
‡ Unassessable: The report cannot be assessed for causality because there is insufficient information reported (i.e., unknown time to event, concomitant medications and comorbidities, clinical course and outcome), the information is contradictory, or information provided in the report cannot be supplemented or verified.

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 secukinumab in pediatric patients less than 17 years of age from January 21, 2015 – January 29, 2025, and identified 25 reports; however, all reports were excluded from further discussion.

[1] Includes two pediatric reports that were identified among reports not coded with an age.

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

5 CONCLUSION

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

6 REFERENCES

1. Cosentyx (secukinumab) injection, for subcutaneous use. [Prescribing information]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: January 2015.
2. Cosentyx (secukinumab) injection, for subcutaneous or intravenous use. East Hanover, NJ; Novartis Pharmaceuticals Corporation: October 2023.
3. Cosentyx (secukinumab) injection, for subcutaneous or intravenous use. [Prescribing information]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: October 2024.
4. Cosentyx (secukinumab) injection, for subcutaneous or intravenous use. [Prescribing information]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: May 2021.

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.