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 2, 2025
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Product Name:	Cibinqo (abrocitinib) tablets
Pediatric Labeling Approval Date:	February 9, 2023
Application Type/Number:	NDA 213871
Applicant:	Pfizer, Inc.
TTT Record ID:	2025-13758

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Cibinqo (abrocitinib) tablets 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 abrocitinib in pediatric patients.

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor initially approved in the U.S. on January 14, 2022. Abrocitinib is currently indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

This pediatric postmarketing safety review was stimulated by pediatric labeling on December 14, 2023, which established the safety and effectiveness of abrocitinib in pediatric patients 12 year of age and older with atopic dermatitis. The safety and effectiveness of abrocitinib have not been established in pediatric patients below 12 years of age.

DPV reviewed all U.S. serious FAERS reports with abrocitinib in pediatric patients less than 18 years of age from January 14, 2022 through March 12, 2025, and identified 15 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 abrocitinib in pediatric patients less than 18 years of age.

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

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Cibinqo (abrocitinib) tablets 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 abrocitinib in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor initially approved in the U.S. on January 14, 2022. Abrocitinib is currently indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

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Abrocitinib has not previously been presented to the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION[1]

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

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS
See full prescribing information for complete boxed warning.

- Increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Discontinue treatment with CIBINQO if serious or opportunistic infection occurs. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.
- Higher rate of all-cause mortality, including sudden cardiovascular death, with another JAK inhibitor vs. TNF blockers in rheumatoid arthritis (RA) patients. CIBINQO is not approved for use in RA patients.
- Malignancies have occurred with CIBINQO. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients.
- MACE has occurred with CIBINQO. Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients.
- Thrombosis has occurred with CIBINQO. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

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

- Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment.

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

- Laboratory Abnormalities: Laboratory monitoring is recommended due to potential changes in platelets, lymphocytes, and lipids.
- Immunizations: Avoid use of live vaccines immediately prior to, during and immediately after CIBINQO treatment.

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

- Most common adverse events (≥1% with CIBINQO 100 mg) are nasopharyngitis, nausea, headache, herpes simplex, increased blood creatine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, impetigo, oropharyngeal pain, hypertension, influenza, gastroenteritis, and dermatitis contact.

- Most common adverse reactions (≥1% with CIBINQO 200 mg and greater than CIBINQO 100 mg) are nausea, headache, herpes simplex, increased blood creatine kinase, dizziness, urinary tract infection, acne, vomiting, gastroenteritis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

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

8.4 Pediatric Use

The safety and effectiveness of CIBINQO in pediatric patients 12 years of age and older with atopic dermatitis have been established.

In trials Trial-AD-1 and Trial-AD-2, 124 pediatric subjects 12 to less than 18 years old weighing 25 kg or more with moderate-to-severe atopic dermatitis were enrolled and randomized to receive either CIBINQO 100 mg (N=51), 200 mg (N=48), or matching placebo (N=25) in monotherapy. Additional 284 pediatric subjects 12 to less than 18 years of age weighing 25 kg or more with moderate-to-severe atopic dermatitis, were enrolled and randomized to receive either CIBINQO 100 mg (N=95) or 200 mg (N=94) or matching placebo (N=95) in combination with topical corticosteroids in Trial-AD-4. Efficacy and adverse reaction profile were comparable between the pediatric patients and adults.

The safety and effectiveness of CIBINQO have not been established in pediatric patients below 12 years of age.

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 13, 2025
Time period of search	January 14, 2022[†] - March 12, 2025
Search type	RxLogix Pediatric Focused Review Alert

Table 1. FAERS Search Strategy*	
Product terms	Product Active Ingredient: abrocitinib
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 Cibinqo (abrocitinib)
‡ 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.
Abbreviation: MedDRA=Medical Dictionary for Regulatory Activities; USA=United States of America

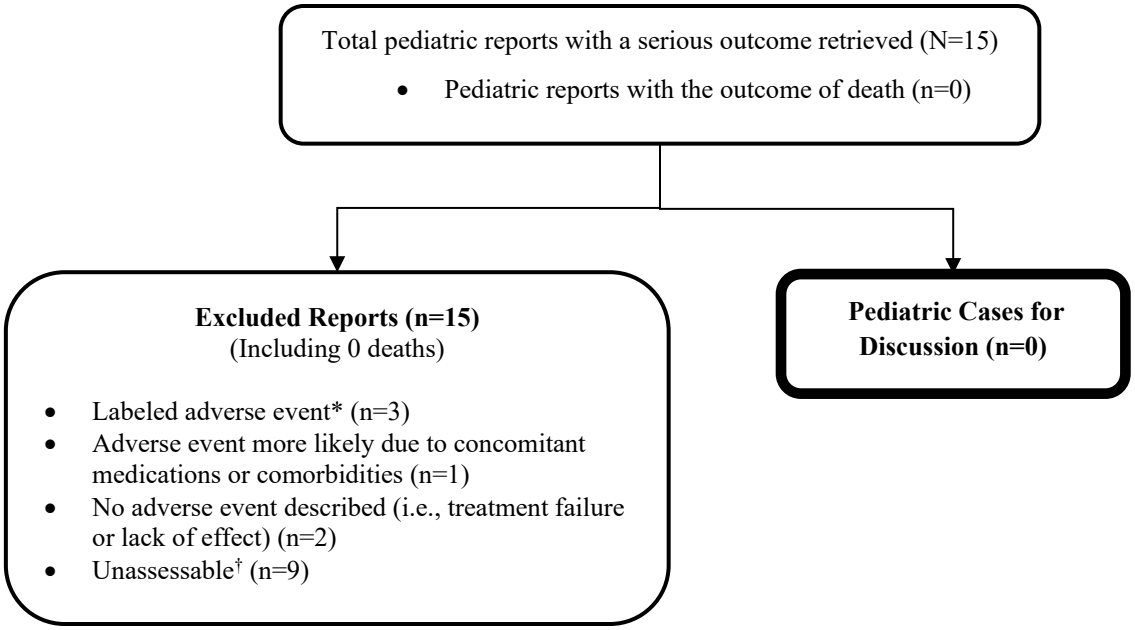
3 RESULTS

3.1 FAERS

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

Our FAERS search retrieved 15 U.S. serious pediatric reports for patients less than 18 years old from January 14, 2022 through March 12, 2025. We reviewed all U.S. FAERS pediatric reports with a serious outcome. We excluded all 15 reports from the case series for the reasons listed in Figure 1.

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



*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 abrocitinib in pediatric patients less than 18 years of age from January 14, 2022 through March 12, 2025, and identified 15 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 abrocitinib in pediatric patients less than 18 years of age.

5 CONCLUSION

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

6 REFERENCES

1. Cibinqo (abrocitinib) [package insert]. New York, NY. Pfizer, Inc. Revised December 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.