



## Pediatric information added to labeling of over 100 drugs, biologics in 2023

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The Food and Drug Administration (FDA) continues efforts to increase the availability of pediatric information in the labeling for drugs and biologics. Between January and December 2023, pediatric information was added to the labeling of more than 75 drugs and 35 biologics, covering a broad range of therapeutic areas.

A pediatric labeling change refers to any update to a product's labeling to add information about safety, effectiveness or dosing in children. Many, but not all, labeling changes represent a new FDA approval for an indication in children.

Several changes in 2023 represent important strides in pediatric product development, including the following:

- **Beyfortus** (nirsevimab-alip) is the first single-dose, long-acting monoclonal antibody approved for the prevention of respiratory syncytial virus lower respiratory tract disease in neonates, infants and certain high-risk toddlers (<https://bit.ly/3PkJmeh>).
- **Casgevy** (exagamglogene autotemcel) and **Lyfgenia** (lovotibeglogene autotemcel) are the first cell-based gene therapies approved for the treatment of sickle cell disease in patients 12 years and older. Casgevy also is the first FDA-approved therapy utilizing CRISPR/Cas9, a type of genome editing technology (<https://bit.ly/3UUocqF>).

- **Jardiance** (empagliflozin) and Synjardy (empagliflozin and metformin hydrochloride) are a new class of treatments approved for treatment of type 2 diabetes in pediatric patients 10 years and older (<https://bit.ly/3ldVAKF>).
- **Linzess** (linaclotide) is the first approved treatment for functional constipation in pediatric patients 6 years and older (<https://bit.ly/3UULzQX>).
- Opvee (nalmefene hydrochloride) is the first nalmefene hydrochloride nasal spray approved for emergency treatment of known or suspected opioid overdose in adults and pediatric patients 12 years and older in a health care or community setting (<https://bit.ly/3Td3zEP>). The FDA also approved the first opioid overdose reversal drugs available over the counter, including the first generic naloxone hydrochloride product, indicated for use in adults and children, including neonates. These approvals are among many actions the FDA has taken as part of its overdose prevention framework (<https://bit.ly/3POET46>).
- **Ycanth** (cantharidin) is the first approved treatment for molluscum contagiosum in adults and pediatric patients 2 years and older, <https://bit.ly/49OFw4B>.

The FDA also took several actions related to mRNA COVID-19 vaccines, including approval of single-dose regimens for the 2023-2024 formula of Comirnaty and Spikevax for individuals 12 years and older (<https://bit.ly/49qyovx>).

In 2023, labeling was updated for 10 products to reflect that safety and effectiveness have been evaluated but *not* established in pediatric patients. Three of the products were evaluated for treatment of major depressive disorder in pediatric patients 7-17 years but failed to establish efficacy: Exxua (gepirone), Fetzima (levomilnacipran) and Trintellix (vortioxetine).

In addition, five products were evaluated for treatment of type 2 diabetes in pediatric patients 10-17 years but failed to establish efficacy: Jentadueto and Jentadueto XR (linagliptin and metformin hydrochloride), Kazano (alogliptin and metformin hydrochloride), Nesina (alogliptin) and Tradjenta (linagliptin).

Other products that failed to demonstrate safety and efficacy in pediatric populations include Savaysa (edoxaban) for treatment of venous thromboembolism and Temodar (temozolomide) for treatment of various central nervous system tumors.

Trade name (generic name)	Indication and labeling change	Pediatric labeling change date
Blincyto (blinatumomab) intravenous injection	Treatment of acute lymphoblastic leukemia in first or second complete remission with minimal residual disease in pediatric patients	June 20, 2023
Cabtreo (clindamycin phosphate, adapalene and benzoyl peroxide) topical gel	Topical treatment of acne vulgaris in adults and pediatric patients 12 years and older	Oct. 20, 2023
*Cresemba (isavuconazonium sulfate) intravenous injection and oral capsules	Treatment of invasive aspergillosis and invasive mucormycosis in pediatric patients: <ul style="list-style-type: none"> <li>• 1 year and older (injection)</li> <li>• 6 years and older and weighing at least 16 kilograms (kg) (capsules)</li> </ul>	Dec. 8, 2023
Ervebo (Ebola Zaire vaccine, live) intramuscular injection	Prevention of disease caused by <i>Zaire ebolavirus</i> in individuals 12 months and older	July 27, 2023
Eylea (aflibercept) intravitreal injection	Treatment of retinopathy of prematurity	Feb. 8, 2023
Focinvez (fosaprepitant) intravenous injection	Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy in adults and pediatric patients 6 months and older	Aug. 22, 2023
Lexapro (escitalopram) oral tablets	Treatment of generalized anxiety disorder in pediatric patients 7 years and older	May 12, 2023
Litfulo (rittlecitinib) oral capsules	Treatment of severe alopecia areata in adults and pediatric patients 12 years and older	June 23, 2023
Nucynta (tapentadol) oral solution and oral tablets	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients 6 years and older and weighing at least 16 kg (solution) or 40 kg (tablets)	July 3, 2023

Trade name (generic name)	Indication and labeling change	Pediatric labeling change date
*Revatio (sildenafil) oral tablets	Treatment of pulmonary arterial hypertension (WHO Group I) in pediatric patients 1-17 years old to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise	Jan. 31, 2023
RizaFilm (rizatriptan) oral film	Acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older weighing at least 40 kg	April 14, 2023
Zinplava (bezlotoxumab) intravenous injection	Reduce recurrence of <i>Clostridioides difficile</i> infection (CDI) in adults and pediatric patients 1 year and older who are receiving antibacterial drug treatment for CDI	May 26, 2023
Zoryve (roflumilast) topical foam	Treatment of seborrheic dermatitis in adults and pediatric patients 9 years and older	Dec. 15, 2023

The FDA's Office of Pediatric Therapeutics and Office of New Drug's Division of Pediatrics and Maternal Health contributed to this article.

### Resources

- [Pediatric labeling changes](#)
- [Orphan drug designations and approvals](#)