

New pediatric labeling information added to 73 products in 2021

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In 2021, new pediatric information was added to the labeling of 73 drug and biological products, including four vaccines, covering a broad range of therapeutic areas (see table).



For many products, the new labeling included information for use in neonates and children younger than 2 years. Studies in these young subpopulations can pose challenges due to the influence of early growth and development on the effect and disposition of an investigational drug and a sometimes-limited understanding of the pathophysiology of disease, particularly for neonates. Obtaining information is vital for appropriate drug use in neonates and young pediatric patients, yet the labeling for many drugs still has insufficient information on safety, efficacy or dosing in these age groups.

Examples of product approvals that included information for use in patients younger than 2 years

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Diovan tablets (valsartan)	Treatment of hypertension in patients 1 year and older	4/19/21
Injectafer injection (ferric carboxymaltose)	Treatment of iron deficiency anemia in patients 1 year and older	11/19/21
Pradaxa oral pellets (dabigatran etexilate)	Treatment of VTE and reduction in the risk of recurrent VTE in patients 3 months and older	6/21/21
Rapivab injection (peramivir)	Treatment of acute uncomplicated influenza in patients 6 months and older	1/28/21
TicoVac suspension for intramuscular injection (tick-borne encephalitis vaccine)	Prevention of tick-borne encephalitis in patients 1 year and older	8/13/21
Zosyn injection (piperacillin/tazobactam)	Treatment of nosocomial pneumonia in patients 2 months and older	7/29/21

Products that included adolescents in the original approval

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Apretude (cabotegravir extended-release injection)	HIV-1 pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in at-risk adolescents weighing at least 35 kilograms	12/20/21
Brexafemme tablets (ibrexafungerp)	Treatment of vulvovaginal candidiasis in post-menarchal females	6/1/21
Comirnaty (COVID-19 vaccine, mRNA)	Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years and older	8/23/21
Nextstellis tablets (drospirenone/estetrol)	Prevention of pregnancy in females of reproductive potential	4/15/21
Opzelura (ruxolitinib)	Treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years and older	9/21/21
Twynéo cream (tretinoin and benzoyl peroxide)	Treatment of acne vulgaris in patients 9 years and older	7/26/21
Xaciatto (clindamycin vaginal gel)	Treatment of bacterial vaginosis in patients 12 years and older	12/7/21

Product approvals that included information for use in all pediatric age groups

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Cleocin Phosphate injection (clindamycin phosphate)	Treatment of serious infections	12/4/21
Dalvance injection (dalbavancin)	Treatment of acute bacterial skin and skin structure infections	7/22/21
Kedrab solution for intramuscular injection (rabies immune globulin [human] passive)	Passive, transient post-exposure prophylaxis of rabies infection	5/17/21
Morphine sulphate injection (morphine sulphate)	Treatment of severe pain requiring an opioid analgesic	4/29/21
Multrys injection (trace elements)	Source of zinc, copper, manganese and selenium for parenteral nutrition	6/30/21
Xarelto oral suspension (rivaroxaban)	Treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE	12/17/21
Zimhi injection for intramuscular or subcutaneous use (naloxone hydrochloride)	Emergency treatment of known or suspected opioid overdose	10/15/21

Additional examples of pediatric approvals in 2021

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Bydureon suspension for T injection (exenatide)	reatment of type 2 diabetes mellitus in patients 10 years and older	7/22/21
Cutaquig solution (immune globulin subcutaneous [human] – hipp)	Treatment of primary humoral immunodeficiency in patients 2 years and older	10/22/21
Dupixent injection (dupilumab)	Treatment of moderate-to-severe asthma in patients 6 years and older	10/20/21
Evekeo ODT (amphetamine sulfate) orally disintegrating tablets	Treatment of attention-deficit/hyperactivity disorder (ADHD) in patients 3 years and older	4/16/21
Natroba topical suspension (spinosad)	Treatment of scabies infestation in patients 4 years and older	4/28/21
Noxafil (posaconazole)	Prophylaxis of invasive aspergillus and candida infections in patients 2 years and older who are at high risk of developing these infections due to being severely immunocompromised	5/31/21
Myrbetriq granules and extended-release tablets (mirabegron)	Treatment of neurogenic detrusor overactivity in patients 3 years and older	3/25/21
Qelbree (viloxazine)	Treatment of ADHD in patients 6 years and older	4/2/21
Ragwitek (short ragweed pollen allergen extract) sublingual	Treatment of short ragweed pollen-induced allergic rhinitis in patients as young as 5 years	4/21/21

For seven products, adolescents were included in the original Food and Drug Administration (FDA) approval. Inclusion of adolescent patients in adult clinical trials has been considered in drug development, when appropriate, to help facilitate more timely access to medicines in this subpopulation. Two original approvals of interest that included adolescents are 1) Apretude (cabotegravir extended-release injection), the first injectable product for HIV-1 pre-exposure prophylaxis in at-risk adolescents weighing at least 35 kilograms, and 2) Comirnaty (COVID-19

vaccine, mRNA), the first vaccine for the prevention of COVID-19 in individuals 16 years and older.

Efficacy was *not* established for some products, including the following:

- Byetta injection (exenatide) for type 2 diabetes mellitus in patients 10-17 years,
- Welchol (colesevelam hydrochloride) for type 2 diabetes mellitus in pediatric patients 10-17 years,
- Vyvanse (lisdexamfetamine dimesylate) for attention-deficit/hyperactivity disorder (ADHD) in patients younger than 6 years,
- AirDuo RespiClick and AirDuo Digihaler inhalation powder (fluticasone propionate/salmeterol xinafoate) for asthma in patients younger than 12 years,
- Austedo (deutetrabenazine) for Tourette's syndrome in patients 6-16 years,
- Cyramza (ramucirumab) for relapsed or refractory solid tumors in patients 1-16 years,
- Aubagio tablets (teriflunomide) for multiple sclerosis in patients 10-17 years, and
- Trintellix (vortioxetine) for major depressive disorder in patients 12-17 years.

For several products, labeling was updated to include important safety information, including for Topicort topical spray (desoximetasone), which is not recommended for use in patients younger than 18 years due to a high incidence of hypothalamic-pituitary-adrenal axis suppression, and Linzess (linaclotide), which is contraindicated in patients younger than 2 years due to risk of serious dehydration based on observations in nonclinical studies in neonatal mice.

The FDA's Office of Pediatric Therapeutics (OPT) and Division of Pediatric and Maternal Health (DPMH) contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine within the Office of New Drugs in the Center for Drug Evaluation and Research.

Resources

- See the FDA-approved labeling for details on each product listed in this article.
- [Pediatric labeling changes](#)