



Pediatric information added to labels of 48 products in 2018

by from the Food and Drug Administration's Office of Pediatric Therapeutics, the Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health and the Center for Biologics Evaluation and Research

New pediatric information was added to the labeling of 43 drugs, two vaccines, one allergen extract and two blood products in 2018.

The approved agents to treat pediatric patients continue to cover a broad spectrum of therapeutic areas (see table).

- There are new pediatric drug therapies for conditions, including: Philadelphia chromosome-positive acute lymphoblastic leukemia; visualization of vessels, blood flow and tissue perfusion before, during and after various surgical procedures; cataplexy or excessive daytime sleepiness; influenza; asthma; attention-deficit/hyperactivity disorder (ADHD); Lyme disease; multiple sclerosis; major depressive episodes associated with bipolar I disorder; and tinea pedis and tinea cruris.
- A new influenza vaccine, Fluarix Quadrivalent*, was approved for immunization of people 6 months and older for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.
- New subcutaneous dosing and administration for Actemra (tocilizumab) for active systemic juvenile idiopathic arthritis in patients 2 years and older was approved.
- A new extended-release capsule, Jornay PM (methylphenidate), was approved for ADHD.

Studies of five drugs did *not* demonstrate efficacy in pediatric patients, including Botox (onabotulinumtoxinA) for the prevention of headaches in adolescents with chronic migraine, Yondelis injection (trabectedin) for pediatric histotypes of sarcoma, Amitiza (lubiprostone) for pediatric functional constipation, Cialis (tadalafil) for Duchenne muscular dystrophy and Pristiq (desvenlafaxine) for the treatment of major depressive disorder.

Examples of products with pediatric labeling changes

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Drugs Sprycel (dasatinib)	Treatment of pediatric patients 1 year and older with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy	December 2018
Spy Agent Green (indocyanine green)	Visualization of vessels, blood flow and tissue perfusion before, during and after various surgical procedures, including minimally invasive surgeries and visualization of extrahepatic biliary ducts in pediatric patients 1 month and older	November 2018
Xyrem (sodium oxybate)	Treatment of cataplexy or excessive daytime sleepiness in pediatric patients 7 years and older with narcolepsy	October 2018
Xofluza	Treatment of acute, uncomplicated influenza in	October



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(baloxavir marboxil)	patients 12 years and older who have been symptomatic for no more than 48 hours	2018
Dupixent (dupilumab)	Add-on maintenance treatment in patients ages 12 years and older with moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma	October 2018
Jornay PM (methylphenidate)	Treatment of attention-deficit/hyperactivity disorder in pediatric patients ages 6-17 years	August 2018
LymePak (doxycycline hyclate)	Treatment of early Lyme disease due to <i>Borrelia burgdorferi</i> in adults and pediatric patients 8 years and older weighing at least 45 kilograms	June 2018
Gilenya (fingolimod)	Treatment of relapsing forms of multiple sclerosis in pediatric patients 10 years and older	May 2018
Latuda (lurasidone hydrochloride)	Treatment of children and adolescents 10-17 years with major depressive episodes associated with bipolar I disorder	March 2018
Luzu Cream (luliconazole)	Treatment of tinea pedis and tinea cruris in pediatric patients 12 years and older	February 2018
Allergenic products		
Oralair* (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Bluegrass Mixed Pollen Allergen Extract)	Immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five-grass species contained in this product in people 5 through 65 years	November 2018

*Products regulated by the Center for Biologics Evaluation and Research

Resources

- [Information on pediatric labeling changes since 1998](#)
- [Additional FDA Update columns](#)