



THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS

AAP News

Pediatric information added to labeling for 80 drugs, vaccines, blood products

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



The Food and Drug Administration (FDA) continues efforts to increase the availability of pediatric information in therapeutic product labeling. From January 2019 through April 2020, new pediatric information was added to the labeling of 74 drugs, one allergenic product, two vaccines and three blood products, covering a broad range of therapeutic areas (see table).

For some products, the new pediatric information represents the first approval in pediatric patients with the indicated condition, including:

- chronic hepatitis C virus (HCV) infection, including genotypes 1, 4, 5 and 6 (Eplclusa [sofosbuvir/velpatasvir] and Harvoni [ledipasvir/sofosbuvir]);
- fibromyalgia (Cymbalta [duloxetine]);
- stable symptomatic heart failure due to dilated cardiomyopathy (Corlanor [ivabradine]);
- symptomatic heart failure with systemic left ventricular systolic dysfunction (Entresto [sacubitril/valsartan]) and
- systemic lupus erythematosus (Benlysta [belimumab]).

The FDA approved new pediatric-friendly dosage forms for several products, including oral pellets for treatment of pediatric patients 3 years and older with chronic HCV infection (Harvoni [ledipasvir/sofosbuvir] and Sovaldi [sofosbuvir]); an oral solution for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months and older (Corlanor Oral Solution [ivabradine]); and a nasal powder for treatment of severe hypoglycemia in pediatric patients 4 years and older with diabetes (Baqsimi [glucagon]).

New pediatric labeling for caffeine citrate (Cafcit Injection), clindamycin (Cleocin Phosphate) and doxycycline (Actilate, Actilate Cap, Doryx, Doryx MPC, Vibramycin, Vibra-Tabs) resulted from studies conducted by the Pediatric Trials Network under the Best Pharmaceuticals for Children Act (BPCA). In collaboration with the National Institute of Child Health and Human Development, BPCA provides a mechanism to study drugs that no longer are under patent to obtain pediatric dosing, safety or efficacy data.

Revised labeling for caffeine citrate now allows for a broader gestational age range and longer duration for treatment of apnea of prematurity. Revised labeling for clindamycin and doxycycline now includes weight-based dosing recommendations for oral and intravenous dosage forms.

Pediatric studies did *not* demonstrate efficacy for seven drugs: Abraxane (paclitaxel) for recurrent or refractory pediatric solid tumors, Opana (oxymorphone hydrochloride) for postoperative pain, Mydayis (mixed salts of a single-entity amphetamine) for attention-deficit/hyperactivity disorder (ADHD) in pediatric patients 12 years and younger, Aptensio XR (methylphenidate hydrochloride) for ADHD in pediatric patients 6 years and younger, Sutent (sunitinib malate) for refractory solid tumors, Chantix (varenicline) as an aid to smoking cessation



treatment and Viibryd (vilazodone hydrochloride) for major depressive disorder.

Examples of products with new pediatric labeling changes

Trade name (generic name)	Indication and labeling change	P e d i a t r i c labeling date
Drugs		
Avycaz (ceftazidime/ avibactam)	Complicated urinary tract infection and complicated intra-abdominal infection in pediatric patients 3 months and older	March 2019
Baqsimi Nasal Powder (glucagon)	Severe hypoglycemia in pediatric patients with diabetes 4 years and older	July 2019
Benlysta (belimumab)*	Active, auto-antibody positive systemic lupus erythematosus in pediatric patients 5 years and older	April 2019
Cafcit (caffeine citrate) Injection	Apnea of prematurity Previously indicated for short-term use in infants 28 to less than 32 weeks gestational age (GA) New labeling information: <ul style="list-style-type: none"> • Lower and upper GA limits were removed to include a broader range of premature infants • The term "short-term" was removed, allowing for a longer treatment duration 	March 2020
Corlanor Oral Solution (ivabradine)*	Stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients 6 months and older	April 2019
Cymbalta (duloxetine)*	Fibromyalgia in pediatric patients 13 years and older	April 2020
Descovy (emtricitabine/ tenofovir alafenamide)	HIV-1 pre-exposure prophylaxis in at-risk adolescents weighing at least 35 kilograms (kg)	October 2019
Entresto (sacubitril/ valsartan)*	Symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients 1 year and older	October 2019
Epclusa (sofosbuvir/ velpatasvir)*	Chronic hepatitis C virus genotype 1, 2, 3, 4, 5 or 6 infection in pediatric patients 6 years and older weighing at least 17 kg	March 2020
Fiasp (insulin aspart)	Diabetes mellitus in pediatric patients	December 2019
Harvoni (ledipasvir/ sofosbuvir)*	Chronic hepatitis C virus genotype 1, 4, 5 or 6 infection in pediatric patients 3 years and older	November 2019



Sorilux (calcipotriene) Topical	Plaque psoriasis of the scalp and body in pediatric patients 4 years and older	November 2019
Teflaro (ceftaroline fosamil) Injection	Acute bacterial skin and skin structure infections in pediatric patients at least 34 weeks gestational age and 12 days postnatal age to less than 2 years	September 2019
Zovirax (acyclovir) Injection	Neonatal herpes simplex virus infection Updated dosing regimen: <ul style="list-style-type: none"> • 20 mg/kg every 8 hours for 21 days for post-menstrual age (PMA) 34 weeks • 20 mg/kg every 12 hours for 21 days for PMA <34 weeks 	January 2019
Allergenic product		
Palforzia (Peanut [Arachisanaphylaxis, that may occur with accidental hypogaea] Allergen Powder-dnfp)	Mitigation of allergic reactions, including exposure to peanut in pediatric patients 4 years and older with a confirmed diagnosis of peanut allergy	January 2020
Vaccine		
Dengvaxia (Dengue Tetravalent Vaccine, Live)	Prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in pediatric patients 9 years and older	May 2019

* First approval in pediatric patients with the indicated condition

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