



FDA Update, News Articles, Pharmacology

New pediatric labeling information available for 53 products

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

New pediatric information was added to the labeling of 48 drugs, two vaccines, two blood products and one allergenic product in 2017. The approved agents to treat pediatric patients continue to cover a broad spectrum of therapeutic areas (see table).

New pediatric drug therapies are available for the following conditions:

- impetigo,
- HIV,
- partial-onset seizures,
- chronic hepatitis B virus infection,
- psoriasis,
- acute uncomplicated influenza,
- chronic hepatitis C and
- polyarticular juvenile idiopathic arthritis.

A new blood product, Fibryna, was approved. The human fibrinogen concentrate is indicated for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Important safety information was added to Tekturna (aliskiren) approved for the treatment of hypertension. Tekturna is contraindicated in children younger than 2 years of age and should not be used in children ages 2 to 6 years or in children who weigh less than 20 kilograms.

New pediatric formulations of several drugs were approved, including Cotempla XR ODT (methylphenidate), an orally disintegrating tablet, extended-release formulation to treat attention-deficit/hyperactivity disorder (ADHD), and Isentress (raltegravir), an oral suspension for HIV-1 infection in combination with other antiretrovirals.

Studies of eight drugs did *not* demonstrate efficacy, including:

- Mydayis (mixed salts of a single-entity amphetamine) for the treatment of ADHD in pediatric patients younger than 12 years of age,
- Latuda (lurasidone hydrochloride) for the treatment of schizophrenia in adolescents and irritability associated with autistic disorder in pediatric patients,
- Ofirmev (acetaminophen) for the treatment of pain in pediatric patients from birth to 2 years,
- Butrans transdermal system (buprenorphine) for the treatment of moderate to severe chronic pain requiring around-the-clock opioid treatment for an extended period of time,
- Simponi (golimumab) for the treatment of active polyarticular juvenile idiopathic arthritis,
- Jakafi (ruxolitinib) for the treatment of relapsed or refractory solid tumors, leukemias or myeloproliferative neoplasms,
- Sensipar (cinacalcet) for the treatment of secondary hyperparathyroidism in pediatric patients with chronic kidney disease on dialysis, and



FDA Update, News Articles, Pharmacology

- Jevtana (cabazitaxel) for the treatment of solid tumors.

Examples of products with new pediatric labeling changes

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Drugs		
Xepi (ozenoxacin)	Impetigo in adults, adolescents and children 2 months and older	December 2017
Isentress (raltegravir)	HIV-exposed neonates ages 0-4 weeks and weighing at least 2 kg	November 2017
Vimpat (lacosamide)	Treatment of partial-onset seizures in patients 4 years of age and older	November 2017
Pegaspas (Pegfilgrastim)	Treatment of non-cirrhotic pediatric patients 3 years of age and older with HBsAg-positive chronic hepatitis B virus infection	October 2017
Stelara (ustekinumab)	Treatment of moderate to severe plaque psoriasis in adolescents ages 12 years or older	October 2017
Rapivab (peramivir)	Acute uncomplicated influenza in patients 2 years and older	September 2017
Fycompa (perampanel)	Monotherapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy ages 12 years and older	July 2017
Harvoni (ledipasvir and sofosbuvir)	Treatment of chronic hepatitis C virus genotype 1, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis in pediatric patients 12 years of age and older or weighing at least 35 kg	April 2017
Orencia (abatacept)	Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older	March 2017
Allergenic product		
Rubber Panel T.R.U.E. TEST (Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test*)	An aid in the diagnosis of allergic contact dermatitis in patients 6 years of age and older whose history suggests sensitivity to one or more of the 5 substances included on the test	March 2017
Blood product		
Fibryna* Fibrinogen (Human)	A human fibrinogen concentrate indicated for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia	June 2017



THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS

AAP News

FDA Update, News Articles, Pharmacology

and hypofibrinogenemia

* Products regulated by the FDA's Center for Biologics Evaluation and Research

Resources

- [Information on pediatric labeling changes since 1998](#)