

Drug Name	Label Update Summary
Propylthiouracil	<p data-bbox="449 238 1854 375">A Black Box Warning was added to inform that propylthiouracil carries a serious risk of severe liver injury, including liver failure and death, in both adults and children. It should be used only when methimazole is not tolerated and other treatments (radioactive iodine or surgery) are not suitable. Because methimazole can cause fetal abnormalities, propylthiouracil may be preferred during or just before the first trimester of pregnancy.</p> <p data-bbox="449 418 1845 625">The Pediatric Use section was updated to inform that severe liver injury, including liver failure requiring transplant or resulting in death, has been reported in children taking propylthiouracil, with no similar reports for methimazole. Because of this risk, propylthiouracil should be avoided in pediatric patients except in rare cases where methimazole is not tolerated and other treatments are unsuitable. Families should be informed of the liver-failure risk, and the drug should be stopped immediately—and labs obtained—if symptoms such as fatigue, nausea, anorexia, fever, sore throat, or malaise occur.</p>
Pralidoxime	<p data-bbox="449 639 1839 813">The Pharmacokinetics section was updated to include the following study results. In 11 children treated for organophosphate poisoning, pralidoxime was given as a loading dose followed by a continuous infusion for about a day. This dosing produced steady-state levels around 22 mg/L, with drug clearance averaging 0.88 L/kg/hr. After the infusion stopped, pralidoxime had a volume of distribution of 1.7–13.8 L/kg and a half-life of 2.4–5.3 hours.</p> <p data-bbox="449 857 1854 997">The Pediatric Use section was updated to indicate that pralidoxime efficacy in children has not been proven in controlled trials; efficacy has been extrapolated from adults and supported by limited data. Rapid IV injection can cause serious reactions such as laryngospasm, cardiac arrest, tachycardia, muscle rigidity or paralysis, as well as fasciculations, apnea, and convulsions.</p>
Sodium Nitroprusside	<p data-bbox="449 1050 1791 1117">The Pediatric Use section was updated to relay that pediatric efficacy was inferred from adult studies and supported by two pediatric trials using sodium nitroprusside. No new safety concerns were identified.</p> <p data-bbox="449 1161 1845 1312">The Clinical Pharmacology section now includes results from two pediatric trials which showed that sodium nitroprusside effectively lowered mean arterial pressure across all age groups, including very young children. A dose-ranging study (Study 1) showed mean arterial pressure reductions of 11–20 mmHg, and a long-term infusion study (Study 2) confirmed effectiveness for at least 12 hours.</p>

Meropenem	The indication and dosing for meropenem were updated for pediatric patients under 3 months with intra-abdominal infections. Dosing is now based on gestational and postnatal age, and the drug is recommended to be infused over 30 minutes.
Mercy Tape device (2D and 3D models)	The Mercy TAPE device received 510(k) clearance to estimate body weight in children aged 2 months to 16 years using arm measurements—humeral length (or half-humeral length in the 3D model) and mid-upper arm circumference. It may be less reliable in children with limb deformities or abnormal body proportions, such as those with edema or severe malnutrition. The estimated weight can be read directly from the tape color.
Lisinopril	When researchers compared how much lisinopril the body is exposed to (after adjusting for dose) in children with kidney transplants and without, the levels were similar. The label now indicates that having a kidney transplant did not change how lisinopril is processed.
Lorazepam	The Pediatric Use section was updated to indicate that lorazepam has not been shown effective for pediatric status epilepticus. The label now includes results from a large trial which showed it was no better than diazepam and caused more sedation and slower recovery. Paradoxical excitation and, rarely, seizures have been reported in children after exposure to lorazepam.
Ampicillin	Ampicillin half-life decreases as renal function matures in infants under 28 days. For neonates $\leq 28$ days with meningitis or septicemia, dosing is now based on gestational and postnatal age.
Lithium	Lithium can be used to treat bipolar disease in children. The label now includes an age range, dosing suggestions and information on obtaining serum lithium concentrations.
Acyclovir	Acyclovir is commonly used to treat neonatal herpes simplex virus (HSV), which if untreated, carries a high risk of death among newborns. The label now includes information on pharmacokinetics and dosing for neonates from birth to 3 months.
Mercy Baby Tape	Mercy babyTAPE received 510(k) clearance for use in estimating the body weight of pediatric patients from birth to 90 days using the Mercy TAPE device.
Doxycycline	Doxycycline is commonly used to treat life-threatening infectious diseases in children up to 8 years of age. Updates to the label included pharmacokinetic information for IV and oral formulations in patients 2-18 years of age showing that children between 2 and 8 years of age can tolerate the same per kg dosing of oral and intravenous doxycycline as children older than 8 years of age without significant adverse outcomes.

Clindamycin	<p><b><u>Obesity Related Change:</u></b> Clindamycin is commonly used to treat serious infections in children. Updates to the label include instructions for dosing based on body weight in both obese and non-obese patients.</p> <p><b><u>Peds Less than 1 month:</u></b> Clindamycin is commonly used to treat serious infections in children. Updates to the label include pharmacokinetic information and dosing guidance for post-menstrual age (PMA) less than or equal to 32 weeks, or greater than 32 weeks to less than or equal to 40 weeks.</p>
TMP-SMX	Trimethoprim-Sulfamethoxazole (TMP-SMX) is approved for the treatment of urinary tract infections, shigellosis, acute middle ear infections, and Pneumocystis jiroveci infections in children 2 months of age and older, and as preventative care against susceptible bacteria. TMP-SMX is commonly prescribed off-label to treat community-acquired methicillin-resistant Staphylococcus aureus infections. Updates to the label include addition of pharmacokinetics information for pediatric patients.
Caffeine Citrate	Caffeine citrate is used for the treatment of apnea of prematurity in preterm infants. Updates to the labeling include indications for use statement to remove use for short term treatment only, and additional information under the warning for necrotizing enterocolitis.
Diazepam	Diazepam is commonly used to treat children with status epilepticus. Updated label changes included pharmacokinetic information and dosing recommendations for children 3 months to 17 years of age.