

Proton Pump Inhibitors: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Pediatric Patients

The U.S. Food and Drug Administration (FDA)-approved indications and dosages for the use of proton pump inhibitors (PPIs) in pediatric patients are provided in this table. You can find information on the generic availability of PPIs by searching the Electronic Orange Book at <https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> on the FDA website.



Medication	Indication	Age	Weight	Dosage	Other Information	Generic Availability
esomeprazole[1]	EE	1 month to less than 1 year old	3 to 5 kg	2.5 mg once a day for up to 6 weeks	Doses over 1.33 per mg per kg per day have not been studied.	Yes
esomeprazole	EE	1 month to less than 1 year old	More than 5 kg to 7.5 kg	5 mg once a day for up to 6 weeks	Doses over 1.33 per mg per kg per day have not been studied.	Yes
esomeprazole	EE	1 month to less than 1 year old	More than 7.5 kg to 12 kg	10 mg once a day for up to 6 weeks	Doses over 1.33 per mg per kg per day have not been studied.	Yes
esomeprazole	EE	1 to 11 years old*	Less than 20 kg	10 mg once a day for 8 weeks	Doses over 1 per mg per kg per day have not been studied.	Yes
esomeprazole	EE	1 to 11 years old*	20 kg or more	10 mg or 20 mg once a day for 8 weeks	Doses over 1 per mg per kg per day have not been studied.	Yes
esomeprazole	EE	12 to 17 years old	All weights	20 mg or 40 mg once a day for 4 to 8 weeks.	No additional information.	Yes
esomeprazole	GERD	1 to 11 years old*	All weights	10 mg once a day for up to 8 weeks	Doses over 1 per mg per kg per day have not been studied.	Yes
esomeprazole	GERD	12 to 17 years old	All weights	20 mg once a day for up to 8 weeks	No additional information.	Yes
lansoprazole[2]	EE	1 to 11 years old	30 kg or less	15 mg once a day for up to 12 weeks*	The PREVACID® dose was increased (up to 30 mg twice daily) in some pediatric patients after 2 or more weeks of treatment if they remained symptomatic.	Yes

Medication	Indication	Age	Weight	Dosage	Other Information	Generic Availability
lansoprazole	EE	1 to 11 years old	More than 30 kg	30 mg once a day for up to 12 weeks*	The PREVACID dose was increased (up to 30 mg twice daily) in some pediatric patients after 2 or more weeks of treatment if they remained symptomatic.	Yes
lansoprazole	EE	12 to 17 years old	All weights	30 mg once a day for up to 8 weeks	No additional information.	Yes
lansoprazole	GERD	1 to 11 years old	30 kg or less	15 mg once a day for up to 12 weeks*	The PREVACID dose was increased (up to 30 mg twice daily) in some pediatric patients after 2 or more weeks of treatment if they remained symptomatic.	Yes
lansoprazole	GERD	1 to 11 years old	More than 30 kg	30 mg once a day for up to 12 weeks*	The PREVACID dose was increased (up to 30 mg twice daily) in some pediatric patients after 2 or more weeks of treatment if they remained symptomatic.	Yes
lansoprazole	GERD	12 to 17 years old	All weights	15 mg once a day for up to 8 weeks	No additional information.	Yes
omeprazole[3]	EE	1 to 16 years old	5 kg to less than 10 kg	5 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†
omeprazole	EE	1 to 16 years old	10 kg to less than 20 kg	10 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†
omeprazole	EE	1 to 16 years old	20 kg or more	20 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†

Medication	Indication	Age	Weight	Dosage	Other Information	Generic Availability
omeprazole	GERD	1 to 16 years old	5 kg to less than 10 kg	5 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†
omeprazole	GERD	1 to 16 years old	10 kg to less than 20 kg	10 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†
omeprazole	GERD	1 to 16 years old	20 kg or more	20 mg once a day	Pellets in capsule may be emptied into one tablespoon of applesauce, mixed together, and eaten, followed immediately by a glass of water.	Yes†
pantoprazole‡[4]	EE	5 years old and older	15 kg up to 40 kg	20 mg once a day for up to 8 weeks§	Pantoprazole is FDA-approved for the treatment of EE associated with GERD.	Yes
pantoprazole‡	EE	5 years old and older	40 kg or more	40 mg once a day for up to 8 weeks§	Pantoprazole is FDA-approved for the treatment of EE associated with GERD.	Yes
rabeprazole[5]	GERD	1 to 11 years old	Less than 15 kg	5 mg once a day for up to 12 weeks (option to increase to 10 mg if inadequate response)	No additional information.	Yes
rabeprazole	GERD	1 to 11 years old	15 kg or more	10 mg once a day for up to 12 weeks	No additional information.	Yes
rabeprazole	GERD	12 years old and older	All weights	20 mg once a day for up to 8 weeks	No additional information.	Yes

EE = erosive esophagitis GERD = gastroesophageal reflux disease

* The PREVACID dose was increased (up to 30 mg twice daily) in some pediatric patients after 2 weeks or more of treatment if they remained symptomatic.

† Prilosec® (omeprazole) for delayed-release oral suspension is not available in a generic formulation.

‡ Pantoprazole is FDA-approved for the treatment of EE associated with GERD.

§ Safety of treatment beyond 8 weeks in pediatric patients has not been established.

To see the electronic version of this dosing table and the other products included in the “Proton Pump Inhibitors” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/pharmacy-ed-materials.html> on the Centers for Medicare & Medicaid Services (CMS) website.

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References

- 1 Nexium® (esomeprazole) prescribing information. (2014, December 19). Retrieved August 17, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022101s014021957s017021153s050lbl.pdf
- 2 PREVACID® (lansoprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021428s028lbl020406s081lbl.pdf
- 3 Prilosec® (omeprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022056s017lbl019810s101lbl.pdf
- 4 Protonix® (pantoprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022020s011-020987s049lbl.pdf
- 5 AcipHex® (rabeprazole) prescribing information. (2014, December 19). Retrieved August 21, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020973s035204736s005lbl.pdf

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