

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



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

Indication	dexlansoprazole[1]	esomeprazole[2]	lansoprazole[3, 4]	omeprazole[5, 6]	pantoprazole[7]	rabenprazole[8]
DU, short-term treatment	Not Applicable (N/A)	N/A	15 mg once a day for 4 weeks	20 mg once a day*	N/A	20 mg once a day for up to 4 weeks
DU, maintenance of healed	N/A	N/A	15 mg once a day	N/A	N/A	N/A
DU, H. pylori eradication to reduce the risk of recurrence of	N/A	Triple Therapy: 40 mg once a day for 10 days†	Triple Therapy: 30 mg twice a day for 10 or 14 days† Dual Therapy: 30 mg 3 times a day for 14 days‡	Triple Therapy: 20 mg twice a day for 10 days§ Dual Therapy: 40 mg once a day for 14 days	N/A	Triple Therapy: 20 mg twice a day for 7 days†
EE, healing of	60 mg once a day for up to 8 weeks	20 mg or 40 mg once a day for 4 to 8 weeks#	30 mg once a day for up to 8 weeks#	20 mg once a day for 4 to 8 weeks	40 mg once a day for up to 8 weeks#	N/A
EE, maintenance of healed	30 mg once a day**	20 mg once a day**	15 mg once a day	20 mg once a day††	40 mg once a day††	N/A
GERD, healing of erosive or ulcerative	N/A	N/A	N/A	N/A	N/A	20 mg once a day for 4 to 8 weeks#
GERD, maintenance of healing of erosive or ulcerative	N/A	N/A	N/A	N/A	N/A	20 mg once a day††
GERD, symptomatic (non-erosive)	30 mg once a day for 4 weeks	20 mg once a day for 4 weeks#	15 mg once a day for up to 8 weeks‡‡	20 mg once a day for up to 4 weeks	N/A	20 mg once a day for 4 weeks#
GU, short-term treatment of benign	N/A	N/A	30 mg once a day for up to 8 weeks	40 mg once a day for 4 to 8 weeks	N/A	N/A
GU, healing of NSAID-associated	N/A	N/A	30 mg once a day for up to 8 weeks‡‡	N/A	N/A	N/A

Proton Pump Inhibitors: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Adults (Cont.)

Indication	dexlansoprazole[1]	esomeprazole[2]	lansoprazole[3, 4]	omeprazole[5, 6]	pantoprazole[7]	rabenprazole[8]
GU, risk reduction of NSAID-associated	N/A	20 mg or 40 mg once a day for up to 6 months**	15 mg once a day for up to 12 weeks‡‡	N/A	N/A	N/A
Heartburn, OTC Treatment	N/A	N/A	15 mg once a day for 14 days§§	20 mg once a day for 14 days	N/A	N/A
Pathological hypersecretory conditions	N/A	40 mg twice a day##	60 mg once a day***	60 mg once a day†††	40 mg twice a day##	60 mg once a day‡‡‡
Generic Availability	No	No	Yes§§§	Yes	Yes	No

DU = duodenal ulcer EE = erosive esophagitis GERD = gastroesophageal reflux disease GU = gastric ulcer

NSAID = non-steroidal anti-inflammatory drug OTC = over the counter

* Most patients will heal within four weeks. Some patients may require an additional four weeks of therapy.

† In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for the same duration of treatment as the PPI.

‡ In combination with amoxicillin 1000 mg three times a day for 14 days.

§ In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for 10 days. In patients with an ulcer present at the time of initiation of H. pylori treatment, an additional 18 days of omeprazole 20 mg once a day is recommended for ulcer healing and symptom relief.

|| In combination with clarithromycin 500 mg three times a day for 14 days. In patients with an ulcer present at the time of initiation of H. pylori treatment, an additional 14 days of omeprazole 20 mg once a day is recommended for ulcer healing and symptom relief.

An additional course of therapy may be considered for patients who do not heal after the initial course of therapy. The additional course of therapy should be for the same duration of treatment as the initial course of therapy.

** Controlled studies did not extend beyond six months.

†† Controlled studies did not extend beyond 12 months.

‡‡ Controlled studies did not extend beyond the indicated duration.

§§ Prevacid®24HR (lansoprazole) product packaging states: “You may repeat a 14-day course every 4 months.”

||| Prilosec OTC® (omeprazole) product packaging states: “You may repeat a 14-day course every 4 months.”

Doses up to 240 mg per day have been administered.

*** Doses should be adjusted to individual patient needs. Dosages up to 90 mg twice a day have been administered. Daily dosages greater than 120 mg should be administered in divided doses.

††† Doses should be adjusted to individual patient needs. Dosages up to 120 mg three times a day have been administered. Daily dosages greater than 80 mg should be administered in divided doses.

‡‡‡ Doses should be adjusted to individual patient needs. Dosages up to 100 mg once a day and 60 mg twice a day have been administered.

§§§ An over-the-counter formulation of lansoprazole is available as Prevacid®24HR. A generic formulation is not currently available.

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

References

- 1 Dexilant™ (dexlansoprazole) prescribing information. (2011, June). Retrieved July 26, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022287s008lbl.pdf
- 2 Nexium® (esomeprazole) prescribing information. (2011, June). Retrieved June 23, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022101s007,021153s038,021957s010lbl.pdf
- 3 Prevacid® (lansoprazole) prescribing information. (2011, June). Retrieved June 23, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020406s075,021428s022lbl.pdf
- 4 Prevacid®24 HR (lansoprazole) prescribing information. (2009, August). Retrieved November 5, 2012, from <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=fd4629d5-b876-4ae9-bb32-c3560ad416a9>
- 5 Prilosec® (omeprazole) prescribing information. (2011, June). Retrieved July 22, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022056s007,019810s091lbl.pdf
- 6 Prilosec OTC® (omeprazole) prescribing information. (2011, June). Retrieved November 5, 2012, from <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=77ed80a2-a482-4838-ac55-4865b5c31d9f>
- 7 Protonix® (pantoprazole) prescribing information. (2011, May 20). Retrieved June 23, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020987s041,022020s005lbl.pdf
- 8 Aciphex® (rabeprazole) prescribing information. (2013, April 19). Retrieved June 17, 2013, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020973s032lbl.pdf

Disclaimer

This fact sheet was current at the time it was published or uploaded onto the web. Medicaid and Medicare policies change frequently, so links to the source documents have been provided within the document for your reference.

This fact sheet was prepared as a service to the public and is not intended to grant rights or impose obligations. This fact sheet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. Use of this material is voluntary. Inclusion of a link does not constitute CMS endorsement of the material. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

August 2013

This fact sheet was prepared by the Education Medicaid Integrity Contractor (MIC) for the CMS Medicaid Integrity Program (MIP). For more information on the MIP, please visit <http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/pharmacy-ed-materials.html> on the CMS website or scan the Quick Response (QR) code on the right with your mobile device.

