

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. 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 | Dosing Information | Other Information | Generic Availability |
|--------------------|--|--|--|----------------------|
| dexlansoprazole[1] | EE, healing of | 60 mg once a day for up to 8 weeks | No additional information. | No |
| dexlansoprazole | EE, maintenance of healed | 30 mg once a day | Controlled studies did not extend beyond 6 months. | No |
| dexlansoprazole | GERD, symptomatic (nonerosive) | 30 mg once a day for 4 weeks | No additional information. | No |
| esomeprazole[2] | DU, <i>H. pylori</i> eradication to reduce the risk of recurrence of | Triple therapy: 40 mg once a day for 10 days | In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for 10 days. | Yes |
| esomeprazole | EE, healing of | 20 mg or 40 mg once a day for 4 to 8 weeks | May continue therapy for an additional 4 to 8 weeks if additional healing time is required. | Yes |
| esomeprazole | EE, maintenance of healed | 20 mg once a day | Controlled studies did not extend beyond 6 months. | Yes |
| esomeprazole | GERD, symptomatic (nonerosive) | 20 mg once a day for 4 weeks | If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered. | Yes |
| esomeprazole | GU, risk reduction of NSAID-associated | 20 mg or 40 mg once a day for up to 6 months | Controlled studies did not extend beyond 6 months. | Yes |
| esomeprazole | Pathological hypersecretory conditions | 40 mg twice a day | Dosage regimens should be adjusted to individual patient needs. Doses up to 240 mg per day have been administered. | Yes |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|----------------------|--|---|--|----------------------|
| esomeprazole 24HR[3] | Frequent heartburn; OTC treatment | 22.3 mg once a day for 14 days | You may repeat a 14-day course every 4 months; dose corresponds to 20 mg of regular esomeprazole. | No |
| lansoprazole[4] | DU, short-term treatment | 15 mg once a day for 4 weeks | No additional information. | Yes |
| lansoprazole | DU, maintenance of healed | 15 mg once a day | No additional information. | Yes |
| lansoprazole | DU, <i>H. pylori</i> eradication to reduce the risk of recurrence of | Triple Therapy: 30 mg twice a day for 10 or 14 days; Dual Therapy: 30 mg three times a day for 14 days | Triple Therapy: In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for 10 days; Dual Therapy: In combination with amoxicillin 1000 mg three times a day for 14 days. | Yes |
| lansoprazole | EE, healing of | 30 mg once a day for up to 8 weeks | Patients who do not heal after 8 weeks may benefit from an additional 8 weeks of therapy. If EE recurs, consider an additional 8-week course. | Yes |
| lansoprazole | EE, maintenance of healed | 15 mg once a day | Controlled studies did not extend beyond 12 months. | Yes |
| lansoprazole | GERD, symptomatic (nonerosive) | 15 mg once a day for up to 8 weeks | Controlled studies did not extend beyond the indicated duration. | Yes |
| lansoprazole | GU, short-term treatment of benign | 30 mg once a day for up to 8 weeks | No additional information. | Yes |
| lansoprazole | GU, healing of NSAID-associated | 30 mg once a day for up to 8 weeks | Controlled studies did not extend beyond the indicated duration. | Yes |
| lansoprazole | GU, risk reduction of NSAID-associated | 15 mg once a day for up to 12 weeks | Controlled studies did not extend beyond the indicated duration. | Yes |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|----------------------|--|--|--|----------------------|
| lansoprazole | Pathological hypersecretory conditions | Recommended initial dose: 60 mg once a day | 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. | Yes |
| lansoprazole 24HR[5] | Frequent heartburn, OTC treatment | 15 mg once a day for 14 days | You may repeat a 14-day course every 4 months. | Yes |
| omeprazole[6] | DU, short-term treatment | 20 mg once a day | Most patients heal within 4 weeks. Some patients may require an additional 4 weeks of therapy. | Yes |
| omeprazole | DU, <i>H. pylori</i> eradication to reduce the risk of recurrence of | Triple Therapy: 20 mg twice a day for 10 days; if patient initially presents with an ulcer, extend omeprazole-only therapy 18 days at 20 mg once a day; Dual Therapy: 40 mg once a day for 14 days; if patient initially presents with an ulcer, extend omeprazole-only therapy 14 days at 20 mg once a day | Triple Therapy: In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for 10 days; Dual Therapy: In combination with clarithromycin 500 mg three times a day for 14 days. | Yes |
| omeprazole | EE, healing of | 20 mg once a day for 4 to 8 weeks | If patient does not respond to 8 weeks of therapy, an additional 4 weeks of therapy may be given. If EE recurs, consider additional 4- to 8-week courses. | Yes |
| omeprazole | EE, maintenance of healed | 20 mg once a day | Controlled studies did not extend beyond 12 months. | Yes |
| omeprazole | GERD, symptomatic (nonerosive) | 20 mg once a day for up to 4 weeks | No additional information. | Yes |
| omeprazole | GU, short-term treatment of benign | 40 mg once a day for 4 to 8 weeks | No additional information. | Yes |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|-------------------|--|--|--|----------------------|
| omeprazole | Pathological hypersecretory conditions | Recommended initial dose: 60 mg once a day | 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. | Yes |
| omeprazole OTC[7] | Frequent heartburn, OTC treatment | 20 mg once a day for 14 days | You may repeat a 14-day course every 4 months. | Yes |
| pantoprazole[8] | EE, healing of | 40 mg once a day for up to 8 weeks | May repeat same course of therapy if additional healing time is required. | Yes |
| pantoprazole | EE, maintenance of healed | 40 mg once a day | Controlled studies did not extend beyond 12 months. | Yes |
| pantoprazole | Pathological hypersecretory conditions | 40 mg twice a day | Dosage should be adjusted to individual patient needs. Doses up to 240 mg per day have been administered. | Yes |
| rabeprazole[9] | DU, short-term treatment | 20 mg once a day for up to 4 weeks | Take after morning meal. | Yes |
| rabeprazole | DU, <i>H. pylori</i> eradication to reduce the risk of recurrence of | Triple Therapy: 20 mg twice a day for 7 days | In combination with amoxicillin 1000 mg twice a day and clarithromycin 500 mg twice a day for 7 days. Take with morning and evening meals. | Yes |
| rabeprazole | GERD, healing of erosive or ulcerative | 20 mg once a day for 4 to 8 weeks | May prescribe an additional 8-week course of therapy if additional healing time is required. | Yes |
| rabeprazole | GERD, maintenance of healing of erosive or ulcerative | 20 mg once a day | Controlled studies did not extend beyond 12 months. | Yes |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|-------------|--|--|---|----------------------|
| rabeprazole | GERD, symptomatic (nonerosive) | 20 mg once a day for 4 weeks | May prescribe an additional course of therapy if symptoms do not resolve completely after first 4 weeks. | Yes |
| rabeprazole | Pathological hypersecretory conditions | Recommended initial dose: 60 mg once a day | 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. | Yes |

DU = duodenal ulcer

EE = erosive esophagitis

GERD = gastroesophageal reflux disease

GU = gastric ulcer

OTC = over the counter

NSAID = nonsteroidal anti-inflammatory drug

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 Dexilant™ (dexlansoprazole) prescribing information. (2014, December 19). Retrieved August 17, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022287s019lbl.pdf
- 2 Nexium® (esomeprazole) prescribing information. (2014, December 19). Retrieved August 17, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022101s014021957s017021153s050lbl.pdf
- 3 Nexium® 24HR packaging information. (2015, June 2). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204655Orig1s002lbl.pdf
- 4 PREVACID® (lansoprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021428s028lbl020406s081lbl.pdf
- 5 PREVACID®24HR (lansoprazole) packaging information. (2015, June 30). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022327Orig1s022lbl.pdf
- 6 Prilosec® (omeprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022056s017lbl019810s101lbl.pdf
- 7 Prilosec OTC® (omeprazole) packaging information. (2015, June 22). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021229Orig1s026lbl.pdf
- 8 Protonix® (pantoprazole) prescribing information. (2014, December 19). Retrieved August 20, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022020s011-020987s049lbl.pdf
- 9 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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