

Name(s)

- **Generic:** omeprazole (oh MEP ra zole) | **Brand:** Prilosec, Zegerid, FIRST Omeprazole

Therapeutic Category

- Proton Pump Inhibitor

Indication(s)

1. **Gastroesophageal Reflux Disease (GERD)(erosive or non-erosive):** RX only. Duration of therapy varies based on age and severity. For example, in pt's 1 years and older w/ erosive esophagitis tx duration is up to 6 weeks. If treating symptomatic GERD tx up to 4 weeks.
 2. **Heartburn:** OTC only. Treating uncomplicated heartburn in adults that occurs 2 or more times a week.
 3. **H. pylori eradication:** Rx only. Used in combination with an antibiotic regimen in the treatment of *H. pylori* infections and duodenal ulcers in adults.
 4. **Peptic ulcer disease:** Rx only. Treatment of duodenal or gastric ulcers
 5. **Zollinger-Ellison syndrome:** Rx only. Zollinger-Ellison syndrome is a pathological hypersecretory condition in which the hyper secretions are treated long-term w/ a PPI such as omeprazole.
- OFF LABEL (not covered): Aspiration prophylaxis, Barrett esophagus, Functional Dyspepsia, NSAID-induced ulcers, Stress ulcers...

Dosage Form / Strength / Dosing

- **Dosage Forms:**
 - Delayed Release Capsule: 10 mg, 20 mg, 40 mg
 - Packet: 2.5 mg, 10 mg
 - Delayed Release Tablet: 20 mg
- **Dosing for GERD (erosive or non-erosive)**
 - If mild/intermittent (<2 times per week): 10 mg po qd. Increase to 20 mg qd after 4-8 weeks if needed. D/c after 8 weeks of being asymptomatic
 - If severe and/or frequent (2 or more times per week) and/or erosive esophagitis: 20-40 mg po qd. Continue for 8 weeks once symptoms appear to under control.
 - IF severe erosive esophagitis or Barrett's esophagus: 20 mg po qd for long-term therapy
 - IF symptoms persist AND at 40 mg po qd: 20 mg po bid increasing to 40 mg bid
- **Dosing for Heartburn:** 20 mg po qd for 14 days. May repeat course every 4 months if necessary.
- **Dosing for H. pylori eradication:** 20-40 mg po bid given along with antibiotic regimen. Dose dependent to antibiotic regimen
- **Dosing for Peptic ulcer disease:**
 - Uncomplicated ulcer: 20-40 mg po qd for 4-8 weeks. If refractory/recurrent may increase to 20-40 mg po bid.
 - Complicated ulcer (defined as: perforation, penetration, gastric outlet obstruction): 40 mg po bid for 4 weeks; then 40 mg po qd
- **Dosing for Zollinger-Ellison syndrome:** Initiate 40 mg po bid. May titrate to max of 180 mg per day. Mean dosing appears to be around 60-70 mg per day in two divided doses.
- Dosing for Geriatrics and Pediatrics not covered. Please refer to most current data. Geriatric dosing may need to be decreased due to increased bioavailability in elderly. Pediatric dosing is generally weight-based dosing.



Special Populations / Considerations

- Elimination is decreased and bioavailability is increased in the **Elderly** population so dose adjustment should be made or drug avoided if possible.
- **Patients w/ hepatic impairment** will have bioavailability and half-life increased, and clearance from the plasma decreased.
- In terms of pharmacokinetics the AUC (Area Under the Curve meaning concentration in blood plasma over time) is increased in **Asians**.
- No increased risk of major birth defects shown in pregnancy

Mechanism of Action & Pharmacology

- **Mechanism of Action:** Inhibits the H⁺/K⁺ (Hydrogen/Potassium) ATP pump located in the parietal cells. Gastric basal and stimulated acid secretion are suppressed through proton pump inhibition.
- **Absorption:** Rapid | **Metabolism:** Hepatically primarily through the CYP2C19 pathway and secondarily the 3A4 pathway | **Excretion:** Through the urine with about 77% as metabolites and a tiny amount of the drug unchanged. Also excreted in the feces. Clearance is between 500-600 mL/min and if hepatically impaired clearance decreased to 79 mL/min | **Onset of Action:** Around 1 hour with the peak effect occurring w/in 2 hours | **Time to peak:** In the plasma between 0.5 – 3.5 hours | **Duration of Action:** Around 72 hours w/ 50% of the max effect occurring in 24 hours. Proton pump activity returns to normal over 3-5 days w/ max inhibition around 4 days | **Half-Life Elimination:** 0.5-1 hour w/ healthy hepatic fxn and ~ 3 hours with impaired hepatic fxn | **Protein Binding:** Approx 95%

Side Effects

- **Common:** Headache, stomach pain, nausea, diarrhea, vomiting, gas
- **Serious:** Diarrhea (may be caused by C. diff); Bone fractures in pts taking for 1 year or longer

Drug Interactions

- Some listed drugs are: methotrexate, rifampin, clopidogrel, tacrolimus, digoxin, warfarin, clarithromycin, ketoconazole
- Do not administer w/ other anti-secretory drugs such as H₂-receptor antagonists
- **Avoid strong CYP2C19 inducers**
- Monitor if used with strong CYP2C19 inhibitors

Monitoring Parameters

- Monitor therapy(ies) if used with other drugs that rely on the CYP2C19 pathway
- Magnesium levels

Patient Counseling Information

- May be used to treat GI ulcers, GERD, heartburn and other acid related syndromes.
- OTC treatment duration is 14 days every 4 months.

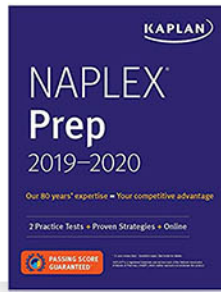
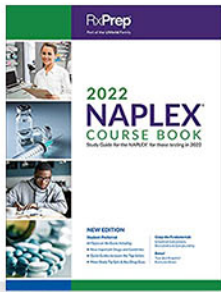
Reference(s)

- <https://www.drugs.com/ppa/omeprazole.html>
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019810s095,022056s011mg.pdf
- <https://www.webmd.com/drugs/2/drug-3766-2250/omeprazole-oral/omeprazole-delayed-release-tablet-oral/details>

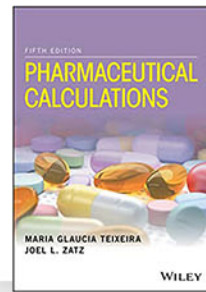
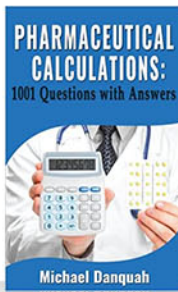
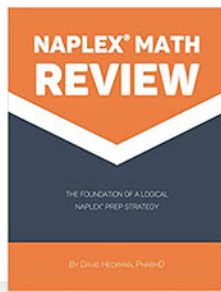
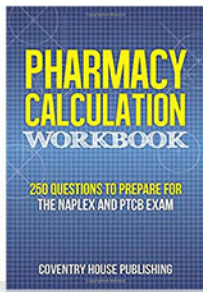


PREPARE FOR SUCCESS!

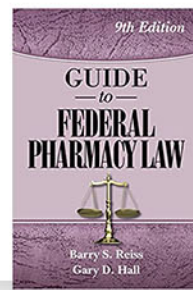
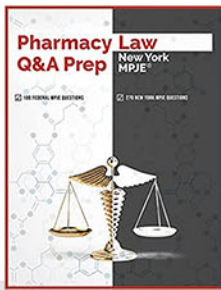
Comprehensive (NAPLEX)



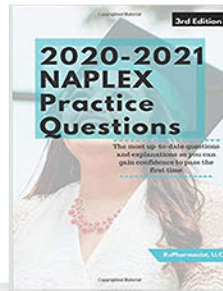
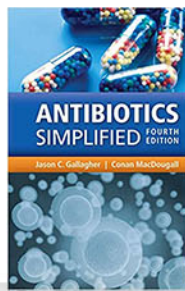
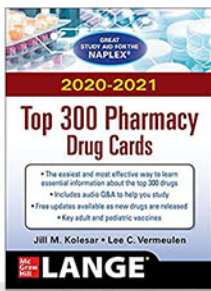
Calculations (NAPLEX)



Pharmacy Law (MPJE)



Supplemental



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Here are some NAPLEX & MPJE prep recommendations to help you do everything you can to **pass the first time!**

HEY STUDENT!

When I was P1 one of the best pieces of advice I got from those before me was to use a NAPLEX Prep book while learning each topic.

This helps focus your learning and the repetition helps to retain info and indirectly prepare you for the NAPLEX



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