

ZEGERID — The First and Only Immediate-Release oral PPI



Now Available

Step One on CareSource

Your PPI choice for nighttime and daytime acid control

- Available in a capsule — and also in a powder for oral suspension¹
 - Both are immediate-release formulations
- ZEGERID offers a distinct pharmacokinetic profile²
 - Rapidly reaches peak plasma levels of omeprazole in **~30 minutes**^{1,2}
 - Gastric pH >4 maintained for a median of **18.6 hours**^{1*}
 - Median values for the time gastric pH >4 for patients taking ZEGERID Powder for Oral Suspension and Capsules, 20 mg and 40 mg doses, **ranged from 12.2 to 18.6 hours on Day 7**
- ZEGERID effectively controls nighttime acid^{3,4†}
- Extensive managed care coverage[‡]



Product Description

ZEGERID[®] (omeprazole/sodium bicarbonate) contains omeprazole, a proton pump inhibitor (PPI), and sodium bicarbonate, an antacid, which raises the gastric pH and thus protects omeprazole from acid degradation.

Indications and Dosing for ZEGERID

ZEGERID is indicated for heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) (20 mg QD); for the short-term treatment (4-8 weeks) of erosive esophagitis diagnosed by endoscopy (20 mg QD); for maintenance of healing of erosive esophagitis (20 mg QD) (controlled studies do not extend beyond 12 months); for short-term treatment (4-8 weeks) of active duodenal ulcer (20 mg QD); for short-term treatment (4-8 weeks) of active benign gastric ulcer (40 mg QD); and for reduction of risk of upper gastrointestinal bleeding in critically ill patients (only powder for oral suspension 40 mg/1680 mg QD; use beyond 14 days has not been evaluated).

The correlation of pharmacodynamic data to clinical effect has not been established.

^{*}The pharmacodynamic study measured the median percentage of time gastric pH >4 as 18.6 hours over 24 hours with ZEGERID 40 mg Powder for Oral Suspension in healthy subjects.

[†]Powder for oral suspension.

[‡]The information provided is not a guarantee of coverage or payment (full or partial). Actual benefits are determined by each plan administrator in accordance with its respective policy and procedures.

Please see full Prescribing Information attached or visit www.zegerid.com.

First and Only Immediate-Release oral PPI

Zegerid[®]
omeprazole/sodium bicarbonate

Rapid release. Continued control.

Coast to coast, ZEGERID has your patients covered



Effective in a wide range of indications

INDICATIONS ¹	QD DOSE ¹	DURATION ¹
Gastroesophageal reflux disease (GERD)		
— Symptomatic GERD with no esophageal lesions	20 mg	Up to 4 weeks
— Erosive esophagitis and accompanying symptoms due to GERD	20 mg	4 to 8 weeks*
Maintenance of healing of erosive esophagitis	20 mg	Controlled studies did not extend beyond 12 months
Short-term treatment of active duodenal ulcer	20 mg	Most patients heal within 4 weeks; some patients may require an additional 4 weeks of therapy
Gastric ulcer	40 mg	4 to 8 weeks
Reduction of risk of upper gastrointestinal bleeding in critically ill patients	40 mg initially, followed by 40 mg after 6 to 8 hours as a loading dose on the first day, then 40 mg once daily. Powder for oral suspension only	Up to 14 days [†]

*The efficacy of ZEGERID used for longer than 8 weeks in these patients has not been established.

[†]Use beyond 14 days has not been evaluated.

Since both 20 mg and 40 mg ZEGERID contain the same amount of sodium bicarbonate (1100 mg in capsules, 1680 mg in packets of powder for oral suspension), two 20 mg capsules are not equivalent to, and should not be substituted for, one 40 mg capsule, and two 20 mg packets are not equivalent to, and should not be substituted for, one 40 mg packet.

Important Safety Information about ZEGERID

The most frequently reported adverse events with ZEGERID are headache, diarrhea, and abdominal pain. In critically ill patients treated with ZEGERID, adverse events generally reflected the serious, underlying medical condition of the patients, and were similar for patients treated with ZEGERID and with the comparator (acid-controlling) drug. Symptomatic response to therapy does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole.

ZEGERID Capsules contain 303 mg of sodium per dose. ZEGERID Powder for Oral Suspension contains 460 mg of sodium per dose. This should be taken into consideration for patients on a sodium-restricted diet. Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia. ZEGERID is contraindicated in patients with known hypersensitivity to any component of the formulation.

References: 1. ZEGERID Prescribing Information. Santarus, Inc. April 2007. 2. Castell D. Review of immediate-release omeprazole for the treatment of gastric acid-related disorders. *Expert Opin Pharmacother.* 2005;6:2501-2510. 3. Castell D, Bagin R, Goldlust B, Major J, Hepburn B. Comparison of the effects of immediate-release omeprazole powder for oral suspension and pantoprazole delayed-release tablets on nocturnal acid breakthrough in patients with symptomatic gastro-oesophageal reflux disease. *Aliment Pharmacol Ther.* 2005;21:1467-1474. 4. Katz PO, Koch FK, Ballard ED, et al. Comparison of the effects of immediate-release omeprazole oral suspension, delayed-release lansoprazole capsules and delayed-release esomeprazole capsules on nocturnal gastric acidity after bedtime dosing in patients with night-time GERD symptoms. *Aliment Pharmacol Ther.* 2007;25:197-205.

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