

# NEW DRUG REVIEW

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## Immediate-Release Omeprazole/Sodium Bicarbonate

Colin W. Howden, MD  
Professor of Medicine  
Northwestern University  
Feinberg School of Medicine  
Chicago, IL

Recently, the US Food and Drug Administration approved a New Drug Application for a capsule formulation of immediate-release omeprazole/sodium bicarbonate (Zegerid, Santarus), the first immediate-release oral proton pump inhibitor (PPI) to become widely available. The following summarizes its key features and some of the data that led to its approval, as well as practical considerations for physicians who may be prescribing this agent.

The most salient feature of immediate-release omeprazole/sodium bicarbonate (as suspension or capsules) is that it is not enteric-coated. Rather than the traditional enteric coating found in delayed-release formulations, this new formulation uses sodium bicarbonate to protect uncoated omeprazole from acid degradation. The potential advantage of this formulation is a more rapid absorption of omeprazole compared to delayed-release omeprazole capsules. More rapid absorption has been associated with more rapid onset of suppression of gastric acidity compared with delayed-release omeprazole capsules.

Omeprazole immediate-release suspension was initially approved as a powder to be mixed with water, a formulation not favored by some patients and physicians. The new capsule formulation may be more acceptable for some patients. Immediate-release omeprazole/sodium bicarbonate (as a suspension or capsule) is approved for the same indications as standard delayed-release omeprazole including the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD), short-term treatment of erosive esophagitis, short-term treatment of active duodenal ulcers, and the maintenance of healing of erosive esophagitis. The 40 mg dose is approved for the treatment of gastric ulcers.

Uniquely for the entire PPI class, immediate-release omeprazole/sodium bicarbonate suspension is approved for the risk reduction of upper gastrointestinal bleeding in critically ill patients. Conrad and colleagues<sup>1</sup> conducted a randomized controlled trial comparing nasogastric or orogastric administration of omeprazole immediate-release suspension with intravenous cimetidine in critically ill

patients. Immediate-release omeprazole suspension was more effective than intravenous cimetidine in maintaining gastric pH above 4. It was not inferior to intravenous cimetidine with respect to the incidence of clinically important upper GI bleeding in critically ill patients.

Castell and colleagues<sup>2</sup> compared the effects of bedtime immediate-release omeprazole suspension and predinner pantoprazole delayed-release tablets on nocturnal intragastric acidity in 36 patients with nocturnal GERD symptoms. Repeated once-daily bedtime administration of immediate-release omeprazole produced significantly better control of nocturnal intragastric acidity than once-daily predinner administration of pantoprazole. Data from a study comparing bedtime administration of omeprazole immediate-release suspension with bedtime administration of lansoprazole (Prevacid, TAP) capsules and esomeprazole (Nexium, AstraZeneca) capsules will be presented at Digestive Disease Week in May, 2006.

Immediate-release omeprazole/sodium bicarbonate (as suspension or capsules) allows for flexible dosing, with the option of administration at night on an empty stomach. It has a rapid onset of action and provides highly effective control of nocturnal intragastric acidity.

So far, there have been no unusual or unexpected side effects with this agent. As with any PPI, there is a small risk of headache, diarrhea, and abdominal pain. This agent contains sodium bicarbonate and may not, therefore, be appropriate for patients who require sodium restriction, such as those with ascites, renal impairment, congestive heart failure, or difficult-to-control hypertension.

### References

1. Conrad SA, Gabrielli A, Margolis B, et al. Randomized, double-blind comparison of immediate-release omeprazole oral suspension versus intravenous cimetidine for the prevention of upper gastrointestinal bleeding in critically ill patients. *Crit Care Med.* 2005;33:760-765.
2. 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 gastroesophageal reflux disease. *Aliment Pharmacol Ther.* 2005;21:1467-1474.