

# pantoprazole available without a prescription

## NEW STATUS

**Better than H2 receptor antagonists, but not for pregnant women**

- When lifestyle measures and antacids are inadequate, and when no alarm symptoms are present, pantoprazole has a better risk-benefit balance than H2 receptor antagonists.



POSSIBLY  
HELPFUL

When an adult patient presents with troublesome symptoms of gastroesophageal reflux, the first measure is to seek and try to rule out the role of food (acidic and spicy foods, alcohol) or drugs (nonsteroidal antiinflammatory drugs, calcium channel blockers, nitrate derivatives, atropinic agents) and to recommend lifestyle modifications (1-3).

**Beware alarm symptoms.** Some clinical signs call for further investigation, such as unexplained weight loss, difficulty swallowing or a sensation of food sticking in the throat, repeated vomiting, gastrointestinal bleeding, anaemia, pain associated with effort, and failure of a previous treatment. After age 50, isolated symptoms of reflux require further investigation, particularly upper gastrointestinal endoscopy (1,3).

### pantoprazole (PANTOZOL CONTROL°)

Tablets

- **20 mg** of pantoprazole per gastroresistant tablet

■ **Licensed indication:** "Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults."

[EU marketing authorisation, centralised procedure]

**gastric antisecretory agent;  
proton pump inhibitor**

**Antacids first.** When drug therapy is envisaged for a patient with no alarm symptoms, antacids should be tried first, as "on demand" therapy during painful episodes (1,3). Several such products are available without a prescription.

If symptoms are mild but frequent and persistent, H2 receptor antagonists are one option. Among such drugs available without a prescription in France, *famotidine* has a better risk-benefit balance than *cimetidine*, which interacts with many other drugs and carries a risk of overdose. The efficacy of H2 receptor antagonists is similar to that of antacids and their adverse effects (diarrhoea, dizziness, headache, fatigue and skin rash) are infrequent.

The most effective drugs are proton pump inhibitors (PPIs), such as *omeprazole* (1,3). In France, *pantoprazole*, a drug first marketed in 1994, is the first PPI to become available without a prescription (and without reimbursement) (4).

**Pantoprazole: positive risk-benefit balance, but risk of interactions.** Clinical assessment of *pantoprazole* in the treatment of gastroesophageal reflux is based on 17 trials in a total of about 6 000 patients (5,6). Heartburn and acid regurgitation disappeared in 60% to 90% of patients after two weeks of treatment with *pantoprazole* 20 mg/day. *Pantoprazole* was more effective than H2 receptor antagonists but not *omeprazole*. About 5% of patients treated with *pantoprazole* had adverse effects commonly seen with other PPIs, mainly diarrhoea, headache and skin rash (2,5,7).

PPIs modify the absorption of substances dependent on gastric pH, such as azole antifungals and antiretroviral drugs. *Pantoprazole* also increases digoxinaemia (2,4).

**Do not use during pregnancy.** Gastroesophageal reflux is very frequent in pregnant women but is generally relieved by non-drug measures (3). If these measures fail, short-course antacid treatment can be tried (1). *Pantoprazole* was found to be foetotoxic in experimental animals and given the lack of human data, its use should therefore be avoided during pregnancy (5,7,8).

**In practice.** For adults aged under 50 who have persistent symptoms of gastroesophageal reflux despite lifestyle measures and antacids, non-prescription *pantoprazole* has a better risk-benefit balance than H2 receptor antagonists.

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**Selected references from Prescrire's literature search.**



In response to our request for information, Nycomed provided us with thorough and relevant documentation.

- 1- Prescrire Rédaction "Reflux gastro-œsophagien chez les adultes (hors prise en charge chirurgicale). Idées-Forces Prescrire" updated January 2008: 7 pages.
- 2- Prescrire Rédaction "6-1. Patients ayant un reflux gastro-œsophagien" *Rev Prescrire* 2008; **28** (302 suppl. drug interactions).
- 3- Prescrire Rédaction "Brûlures d'estomac, remontées acides, chez les adultes" *Rev Prescrire* 2008; **28** (299): 685-686.
- 4- Prescrire Rédaction "Pantoprazole: troisième IPP copié" *Rev Prescrire* 2009; **29** (307): 346.
- 5- EMEA "Assessment Report for Pantecta Control" 8 May 2009: 35 pages.
- 6- Nycomed "Module 2. 2.7.3 Summary of clinical efficacy. Pantoprazole-Na OTC" 20 March 2008: 82 pages.
- 7- Nycomed "Module 2. 2.7.4 Summary of clinical safety. Pantoprazole-Na OTC" 17 April 2008: 57 pages.
- 8- European Commission "Résumé des caractéristiques du produit - Pantoloc Control" 12 June 2009: 10 pages.