

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

KEAL (sucralfate), medicinal product for the treatment of peptic ulcers

Insufficient actual benefit in the treatment of gastric and duodenal ulcers, in view of the more effective treatment alternatives

Main points

- ▶ KEAL has Marketing Authorisation in the treatment of progressive gastric and duodenal ulcers and in the maintenance therapy of duodenal ulcers in patients who are not infected with *Helicobacter pylori* or in whom its eradication has not been possible.
- ▶ It is a gastric coating. It does not have an antisecretory or an antacid action. Its efficacy/adverse effects ratio in the treatment of progressive gastroduodenal ulcers is low.
- ▶ Its role in the therapeutic strategy has become marginal, because of the existence of more effective treatment alternatives in the indications of the Marketing Authorisation.

Therapeutic use

In the case of ulcers due to *H. pylori*, the treatment should be eradication of the bacteria. The majority of ulcers not due to *H. pylori* are associated with treatment with NSAIDs/aspirin. In the absence of infection with *H. Pylori* and the use of NSAIDs, the specific etiology must be investigated (Zollinger-Ellison syndrome, idiopathic acid hypersecretion, Crohn's disease, cancers, infection with *Helicobacter heilmannii* or a CMV, eosinophilic gastroenteritis). For the rare ulcer diseases without a known etiology, the treatment of choice remains antisecretory medicinal products.

The reference treatment for gastric and duodenal ulcers in the presence of *H. pylori* combines antibiotic treatment and an antisecretory drug (PPI). In the absence of *H. Pylori*, an antisecretory drug (proton-pump inhibitor) is recommended, with long-term treatment if necessary.

Maintenance treatment for duodenal ulcers is no longer justified because of the quasi-constant efficacy of the treatments (particularly PPI) and the ability to check for healing (by endoscopy) render maintenance treatment redundant. This situation is different from long-term daily treatment to prevent recurrence.

■ Role of the medicinal product in the therapeutic strategy

KEAL is thus a medicinal product the role of which in the management of gastroduodenal ulcers has become very limited.

Benefit of the medicinal product

- The actual benefit* of KEAL is insufficient in the indications of the Marketing Authorisation.

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.