AstraZeneca

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SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Nexium™
ACTIVE INGREDIENT: Esomeprazole

Developmental phase: IV
First subject recruited: 25 November 2005
Last subject completed: 02 July 2006
Approval date: 21 June 2005

Trial title: Use of esomeprazole in postoperative bariatric surgery patients users and non-users of nonsteroidal anti-inflammatory drugs (NSAIDs)

OBJECTIVES

Primary : To assess the efficacy of Esomeprazole on prevention of anastomotic stomal ulcer after gastric bypass surgery for weight loss

Secondary: To assess the efficacy of Esomeprazole in avoiding appearance of related peptic acid symptoms after gastric bypass surgery for weight loss

Design:

Phase IV, open-label, multicenter, non-randomized, with 2 non-comparative investigational arms study, carried out in morbid obesity patients who had undergone gastric bypass surgery for body weight reduction.
At most 72 hours after surgery, the enrolled patients should begin to receive 20 mg NEXIUM (Esomeprazole) daily for 2 months, preferably in the fasted state, being evaluated for presented symptoms and presence of gastrointestinal lesions by upper digestive endoscopy.
Morbidly obese subjects submitted to gastric bypass surgery for body weight loss, both non-users of nonsteroidal anti-inflammatory drugs (NSAIDs) and chronic users of NSAIDs mainly due to common arthropathies in this population, and which constitute an additional risk factor for presentation of digestive tract lesions will be included in the study.

Population:

Patients of both genders, from 18 years of age and older, and who, along with a physician, have decided to be submitted to bariatric surgery for body weight loss will be selected, provided they fulfill the inclusion criteria.

Key inclusion criteria:

- Written informed consent signed and dated
- Patients older than 18 years
- BMI≥ 40 kg/m^2 or BMI between 35 and 40 kg/m^2, but with a severe disease together with obesity

- Indication for gastric bypass surgery
- Upper digestive endoscopy prior to surgery not showing esophagitis, erosions, ulcers or neoplasia, examination performed up to 30 days before surgery being considered valid
- *Helicobacter pylori* non-infected patients, diagnosed by tests carried out up to 30 days before surgery

Key exclusion criteria:

- Contraindication for gastric bypass surgery
- Contraindication to use Omeprazole and derivatives
- Patients carriers of gastrinoma or having hypergastrinemia
- Patients contraindicated to perform UDE
- Patients with previous esophagogastroduodenal surgery

Dosage:

	NEXIUM	20mg Tablets	oncedaily (preferably up to 10h am)

Formulation and batch numbers were as follows:

20mg NEXIUM, batch numbers – 50865

Efficacy:

- The primary efficacy measure will be the combined percentage for no occurrence of anastomotic stomal ulcer
- Percentagesof no occurrence of acid-peptic symptoms between the 10th and 15th days after surgery,
- Percentdistributions of acid-peptic symptom intensity between the 10th and 15th days, and 2 months after surgery

Pharmokinetics: NOT APPLICABLE
Safety: NOT APPLICABLE.

Reference:

1. *Tratamento cirúrgico da obesidade mórbida.Instituto Garrido de Gastroenterologia e Cirurgia da Obesidade. www.institutogarrido.com.br*
2. *Foster A,Laws HL, Gonzalez QH, Clements RH.Gastrointestinal symptomatic outcome after laparoscopic Roux-en-Y gastric bypass. J Gastrointest Surg 2003;7:750-53*
3. *Pope GD, Goodney PP, Burchard KW, Proia RR, Olafsson A, Lacy BE, Burrows LJ. Peptic ulcer/stricture after gastric bypass: A comparison of technique and acid suppression variables. Obesity Surgery 2002;12(1):30-3*
4. *Elliott SL, Ferris RJ, Giraud AS, Cook GA, Skeljo MV, Yeomans ND.Indomethacin damage to rat gastric mucosa is markedly dpendent on luminal pH.Clin Exp Pharmacol Physiol 1996;23:432-4*
5. *Hawkey CJ, Yeomans ND, Scheiman JM, Talley NJ, Sung JJY, Jones R, Naesdal J, Langstrom G.Maintained symptom control with esomeprazole following initial treatment of upper GI symptoms of patients on NSAIDs including COX-2 selective NSAIDs.Gastroenterology 2004;126(4 Suppl 2):A-609 , Abs W1305*

6. *Yeomans ND, Scheiman JM, Hawkey CJ, Talley NJ,Vakil NB, Naesdal J, Langstrom G.An evidence-based analysis of esomeprazole therapy versus placebo for the prevention of gastric or duodenal ulcers in at risk continuous NSAIDs users.Gatroenterology 2004;126 (4 Suppl 2) : A-604,Abs W1278*
7. *Miner Jr P, Katz PO, Chen Y,Sostek M.Gastric acid control with esomeprazole,lansoprazole, omeprazole, pantoprazole and rabeprazole:a five-way crossover study.Am J Gatroenterol 2003;98:2616-20*
8. *NIH conference.Gastrointestinal surgery for severy obesity.Consensus Development Conference Panel.Ann Intern Med 1991;115:956-61*

As with any comprehensive clinical trial programme, individual studies may include both approved and non-approved treatment regimens, including doses higher than those approved for clinical use. Before prescribing Nexium™ (esomeprazole), Healthcare Professionals should view their specific country information.