

## **PRESCRIBING INFORMATION**

### **NEXIUM® 20mg/40mg Tablets**

**(esomeprazole)**

**Consult Summary of Product Characteristics before prescribing.**

**Use** Gastro Oesophageal Reflux Disease (GORD). *Helicobacter pylori* eradication in combination treatment with antibiotics. Healing of gastric ulcers and prevention of gastric and duodenal ulcers associated with NSAID therapy. Zollinger Ellison Syndrome.

**Presentation** Gastro-resistant tablets containing 20mg or 40mg esomeprazole.

**Dosage and administration Adults (including the elderly) and adolescents:**

#### **NEXIUM®20mg/40mg Tablets**

**GORD:** Adults and adolescents from the age of 12, treatment of Reflux Oesophagitis: 40mg once daily (od) for 4 weeks. An additional 4 weeks treatment is recommended for patients in whom oesophagitis has not healed or who have persistent symptoms. Long-term management of patients with healed oesophagitis to prevent relapse: 20mg od. Symptomatic treatment of GORD: 20mg od (in patients without oesophagitis). If symptoms have not been controlled after 4 weeks, the patient should be further investigated. Once symptoms have resolved, subsequent symptom control can be achieved in adult patients using on-demand Nexium 20mg od, when needed. ***Helicobacter pylori* eradication (in combination with appropriate antibiotics):** Adults only, healing of *H. pylori* associated duodenal ulcers and prevention of relapse of peptic ulcers in patients with *H. pylori* associated ulcers. Nexium 20mg, amoxicillin 1g, clarithromycin 500mg, all twice daily for 7 days.

**Patients requiring continued NSAID therapy:** Adults only, healing of gastric ulcers associated with NSAID therapy: The usual dose is 20mg once daily. The treatment duration is 4-8 weeks. Prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk: 20mg once daily. In NSAID treated patients at risk of developing gastric and duodenal ulcers, subsequent symptom control using an on demand regimen is not recommended. **Treatment of Zollinger Ellison Syndrome:** Adults only, initial dose 40mg bd, then to be individualised., treatment to continue for as long as needed. Patients usually controlled on 80 to 160mg daily doses. Doses above 80mg to be taken bd. **Renal impairment:** No dose adjustment needed. Patients with severe renal insufficiency should be treated with caution. **Hepatic impairment:** No dose adjustment needed except in patients with severe liver impairment where a maximum daily dose of 20mg should not be exceeded. **Adolescents:** Nexium Tablets may be used for GORD in adolescents from the age of 12. **Children below the age of 12 years:** Nexium should not be used in children since no data is available. **Elderly:** No dose adjustment needed.

**Contraindications** Known hypersensitivity to esomeprazole, substituted benzimidazoles or any other constituents of Nexium. Esomeprazole, like other PPIs, should not be administered with atazanavir.

**Special Warnings and Precautions** In the presence of any alarm symptoms and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis. Patients on long-term treatment should be kept under regular surveillance. Patients on on-demand treatment should contact their physician if their symptoms change in character. When prescribing Nexium for on-demand therapy, the implications for interactions with other pharmaceuticals should be considered. When prescribing Nexium for *H. pylori* eradication, possible drug interactions for all components in the triple therapy, particularly clarithromycin, should be considered. Nexium Tablets contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Nexium Tablets. Treatment with proton pump inhibitors may lead to slightly increased risk of

gastrointestinal infections such as Salmonella and Campylobacter. **Interactions with other medicinal products and other forms of interaction** **Effects of Esomeprazole on the pharmacokinetics of other drugs:** Ketoconazole or itraconazole absorption may be reduced. Should not be co-administered with atazanavir (see Contraindications). When Nexium is combined with drugs metabolised by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin, etc. a dose reduction could be needed. This should be considered especially when prescribing Nexium for on-demand therapy. Plasma concentrations of phenytoin should be monitored when treatment with Nexium is introduced or withdrawn. Concomitant treatment of esomeprazole with voriconazole may increase exposure to voriconazole. In warfarin, or other coumarine derivative-treated patients, monitoring is recommended when initiating and ending concomitant treatment. **Effects of other drugs on the pharmacokinetics of esomeprazole:** Concomitant administration of esomeprazole and a CYP3A4 inhibitor, such as clarithromycin, resulted in a doubling of the exposure to esomeprazole. Concomitant administration of esomeprazole and a combined inhibitor of CYP2C19 and CYP 3A4, such as voriconazole, may result in more than doubling of the esomeprazole exposure. A dose adjustment of esomeprazole is not regularly required in either of these situations. However, dose adjustment should be considered in patients with severe hepatic impairment and if long-term treatment is indicated. **Pregnancy & Lactation:** Limited data on exposed pregnancies are available. Avoid in pregnancy unless no safer alternative. It is not known whether esomeprazole is excreted in breast milk. Discontinue breast-feeding if Nexium is considered essential.

**Undesirable events** None of the following were found to be dose-related. **Blood and lymphatic system disorders** - *Rare*: leukopenia, thrombocytopenia; *Very rare*: agranulocytosis, pancytopenia. **Immune system disorders** – *Rare*: hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock. **Metabolism and nutrition disorders** – *Uncommon*: peripheral oedema; *Rare*: hyponatraemia. **Psychiatric disorders** – *Uncommon*: insomnia; *Rare*: agitation, confusion, depression; *Very rare*: aggression, hallucinations. **Nervous system disorders** – *Common*: headache; *Uncommon*: dizziness, paraesthesia, somnolence; *Rare*: taste disturbance. **Eye disorders** - *Rare*: blurred vision. **Ear and labyrinth disorders** – *Uncommon*: vertigo. **Respiratory, thoracic and mediastinal disorders** – *Rare*: bronchospasm. **Gastrointestinal disorders** - *Common*: abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting; *Uncommon*: dry mouth; *Rare*: stomatitis, gastrointestinal candidiasis. **Hepatobiliary disorders** – *Uncommon*: increased liver enzymes; *Rare*: hepatitis with or without jaundice; *Very rare*: hepatic failure, encephalopathy in patients with pre-existing liver disease. **Skin and subcutaneous tissue disorders** – *Uncommon*: dermatitis, pruritus, rash, urticaria; *Rare*: alopecia, photosensitivity; *Very rare*: erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN). **Musculoskeletal, connective tissue and bone disorders** – *Rare*: arthralgia, myalgia; *Very rare*: muscular weakness. **Renal and urinary disorders** – *Very rare*: interstitial nephritis. **Reproductive system and breast disorders** – *Very rare*: gynaecomastia. **General disorders and administration site conditions** – *Rare*: malaise, increased sweating.

**Legal category** POM.

**Marketing authorisation number** Nexium® 20mg Tablets PL 17901/0068; Nexium® 40mg Tablets PL 17901/0069.

**Basic NHS cost** **Tablets 20mg** Blisters of 7 tablets (Hospital pack): £4.63; 28 tablets\*: £18.50; **Tablets 40mg** Blisters of 7 tablets (Hospital Pack): £6.30; 28 tablets\*: £25.19 (\*also available in hospital unit doses).

**Further information is available from the Marketing Authorisation holder**  
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