

**8937-OMEPRAZOL****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Omeprazol

Bulk code: 8937

**1.2 Synonyms.**

No information available.

**2. DESCRIPTION**

Appearance: Powder.

Colour: White or almost white.

Odour: Odourless.

**3. COMPOSITION/INFORMATION ON COMPONENTS.**Formula: C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S

CAS No.: 73590-58-6

Molecular weight: 345.4 g/mol

**4. PHYSICO-CHEMICAL DATA.**

See detailed specifications on analysis certificate.

**Solubility:** Very poorly soluble in water. Soluble in methylene chloride, quite soluble in alcohol and methanol. It dissolves in dilute solutions of alkali hydroxides.

**5. PROPERTIES/USES.**

ACTIVE PHARMACEUTICAL INGREDIENT.

Omeprazole base is a proton pump inhibitor that inhibits gastric acid secretion. It is used to treat reflux oesophagitis, peptic ulcers and Zollinger-Ellison syndrome.

Omeprazole inhibits gastric acid secretion and is considered to do so by irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase, the "proton pump" of the gastric parietal cell.

It is given under conditions where inhibition of gastric acid secretion may be beneficial.

**8937-OMEPRAZOL****6. DOSAGE.**

- Reflux oesophagitis: 20 to 40 mg once daily for 4 to 8 weeks; 20 mg once daily may be continued in subsequent maintenance therapy.
- Peptic ulcers: a single daily dose of 20 mg, or 40 mg in severe cases, is usually recommended for 4 weeks in patients with duodenal ulcers and for 8 weeks in those with gastric ulcers. Treatment for longer periods is not yet recommended.
- Zollinger-Ellison syndrome: usually 60 mg once daily initially, but doses may range from 20 to 120 mg daily; doses above 80 mg should be divided and administered twice daily. In such patients, treatment with omeprazole shall be continued as required to keep the condition under control.

**7. REMARKS.****STORAGE:**

Store in a hermetically sealed container, protected from light, in a refrigerator at a temperature set at  $5 \pm 3^{\circ}\text{C}$ .

**8. BIBLIOGRAPHY.**

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).