METAPHARMACEUTICAL

TECHNICAL DATA SHEET

151367-TDS-ENG-2026

OMEPRAZOL POLVO (EUR. PH.)		
DESCRIPTION DCI: omeprazole	DESCRIPTION DOE: OMEPRAZOL	
CAS Nº: 73590-58-6	EC Nº: 615-996-8	AEMPS CODE: 2141A
MOL. WEIGHT: 345,42	MOL. FORMULA: C17H19N3O3S	ARTICLE CODE: 151367

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96 %) and in methanol. It dissolves in dilute solutions of alkali hydroxides
Identification	Complies
Appearance of solution	Clear
Impurities F and G	
Sum of the contents	=< 350 ppm
Absorvance 440 nm	=< 0.10
Related substances	
Impurity D	=< 0.15 %
Impurity E	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.2 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Keep the product in airtight containers, protected from light and at a temperature between 2-8 °C.

REMARKS

Omeprazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses
OMEPRAZOLE is a proton pump inhibitor. It inhibits gastric acid secretion through an irreversible blockade of the hydrogen / potassium adenosinetriphosphatase enzyme system (the "proton pump") of the gastric parietal cell.

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It is used in processes in which it is useful to inhibit the secretion of gastric acid, such as aspiration syndromes, dyspepsia, gastroesophageal reflux disease, peptic ulcer and Zollinger-Ellison syndrome.

Dosage
Dyspepsia: 10-20 mg / day orally for 2-4 weeks.
Gastroesophageal reflux disease: 20 - 40 mg / day, for 4 - 8 weeks; the maintenance treatment can be continued with 20 mg / day.
Peptic ulcer: 20 mg / day, or 40 mg in severe cases, for 4 weeks in duodenal ulcers and for 8 weeks in gastric ulcers. Treatment is not recommended for longer periods, so OMEPRAZOLE is not used for long-term maintenance.
Eradication of Helicobacter pylori: 20-40 mg / day along with antibiotics.
NSAIDs ulcers: 20 mg / day.
Zollinger-Ellison syndrome: an initial dose of 60 mg / day is recommended, although doses of 20-120 mg / day can be used. In doses higher than 80 mg, it is recommended to divide into two doses. In these patients the treatment is maintained to keep the disease under control.
Acid aspiration during general anesthesia: initial dose of 40 mg the night before plus 40 mg plus 2-6 h before the intervention.

Side effects
The most commonly reported adverse effects are headache, diarrhea and rashes.
Other effects are: pruritus, dizziness, fatigue, constipation, nausea, vomiting, flatulence, abdominal pain, arthralgias and myalgias, urticaria and xerostomia.
Isolated cases of photosensitivity, bullous eruption, erythema multiforme, angioedema and anaphylaxis have been described.
The effects on the CNS consist of occasional insomnia, somnolence and vertigo, as well as reversible confusional states, agitation, depression and hallucinations in seriously ill patients.
Increased liver enzymes and isolated cases of hepatitis, jaundice and hepatic encephalopathy have been reported.
Other adverse effects described exceptionally are: paresthesias, blurred vision, alopecia, stomatitis, sweating, taste alterations, peripheral edema, malaise, hyponatremia, blood disorders and interstitial nephritis.

Precautions
Before prescribing OMEPRAZOLE to patients with gastric ulcers, the presence of cancer should be ruled out, since it can mask some symptoms of other diseases and delay their diagnosis. OMEPRAZOLE is metabolized in the liver so it is recommended to reduce the dose in case of liver failure.
OMEPRAZOLE can inhibit the cytochrome P450 system and alter the metabolism of other drugs metabolized by these enzymes. You can prolong the elimination of diazepam, phenytoin and warfarin. The decrease in gastric acidity caused by OMEPRAZOLE can affect the absorption of other drugs.

Interactions
OMEPRAZOLEE can inhibit the cytochrome P450 system and alter the metabolism of other drugs metabolized by these enzymes. You can prolong the elimination of diazepam, phenytoin and warfarin.
It also reduces the absorption of ketoconazole and possibly itraconazole, since its absorption depends on the gastric acid pH.

Compounding examples

OMEPRAZOLE suspension 2 mg/mL
OMEPRAZOLE - **0.2%**
Sodium bicarbonate - **8-4%**

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Rubber sun xantan. aqueous 1% - **50 mL**
Essence (strawberry, cherry, red berries) **- 0.1-0.3%**
Saccharin sodium - **0.1-0.2%**
Purified water c.s.p. c.s.p. **100 mL**

Modus operandi
1. Slowly disperse 0.5 g of xanthan gum in 50 mL of water under constant agitation. Maintain the agitation until obtaining a homogeneous and complete dispersion. Heat at 50 ºC 2. Disperse 8.4 g of sodium bicarbonate in the water of the formula (P / V). Add the sodium saccharin under constant agitation. This dispersion is not dissolved since it exceeds the saturation concentration.
3. Add the essence to the initial solution of xanthan gum under gentle but constant agitation.
4. Incorporate the solution of xanthan gum and the essence into the bicarbonate and saccharine solution
5. Add the OMEPRAZOLE base and homogenize with a high speed agitator (ultra-turrax type). The final appearance of the suspension is white, homogeneous and viscous, with a pH = 9. Conservation: Stability: the bibliography endorses 56-60 days in a refrigerator in a glass or PET topaz container. It is advisable to date 30 days maximum expiration date. Remarks: Shake before use.

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