



GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

Type of Document:

**TECHNICAL DATA SHEET**

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**4.0**

## **86588-SUCRALFATE**

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

#### 1.1 Identification of the substance or preparation

Name: Sucralfate

Bulk code: 86588

#### 1.2 Synonyms

Sucralfatum; sucrose octakis (hydrogen sulphate) aluminium complex.

### 2. DESCRIPTION

Appearance: Powder

Colour: White or almost white, amorphous

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula:  $C_{12}H_{30}Al_8O_{51}S_8[Al(OH)_3]_n[H_2O]_{n'}$

Where  $n=8$  to  $10$  and  $n'=22$  to  $31$

CAS: 54182-58-0

### 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

**Solubility:** Practically insoluble in water, alcohol and chloroform; soluble in diluted solutions of hydrochloric acid and sodium hydroxide.

### 5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is an aluminium derivative from sucrose with anti-ulcer and protective properties for the digestive mucosa, buffering it and protecting it from the corrosive effects of gastric juice in the damaged area. It also has a mild anti-acid effect.

It is used to treat peptic ulcers and chronic gastritis, and it is administered orally with the stomach empty, either before meals or before going to bed.

It is also used to treat mouth ulcers and oral mucositis caused by radiotherapy.



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### **6. DOSAGE.**

Orally:

- Usual dose: 1 g four times a day, or 2 g every 12 hours, for 4-8 weeks; if necessary, the dose can be increased up to a maximum of 8 g/day. If long-term treatment is required, it can be extended to more than 12 weeks.
- To prevent recurring duodenal ulcers, maintenance doses of 1 g, twice a day, are appropriate.
- For stress ulcer prophylaxis, doses of 1 g are used six times a day. The daily limit of 8 g should not be exceeded.

### **7. REMARKS.**

STORAGE:

Store at room temperature ( $25\pm 2^{\circ}\text{C}$ ), in a cool, dry place, away from sunlight, in a tightly closed container.

### **8. BIBLIOGRAPHY.**

Pharmaceutical Monographs. COF Alicante, 1998.

European Pharmacopoeia Monograph.