METAPHARMACEUTICAL

TECHNICAL DATA SHEET

007903-TDS-ENG-2025

SODIO CROMOGLICATO (EUR. PH.)		
DESCRIPTION DCI: SODIUM CROMOGLICATE	DESCRIPTION DOE: SODIO CROMOGLICATO	
CAS Nº: 15826-37-6	EC Nº: 239-926-7	AEMPS CODE: 698N
MOL. WEIGHT: 512,33	MOL. FORMULA: C23H14Na2O11	ARTICLE CODE: 007903

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, hygroscopic, crystalline powder
Solubility	Soluble in water, practically insoluble in ethanol (96 %)
Identification B	Complies
Identification D	Complies
Appearance of solution	Not more opalescent than ref. sus. II and not more intensely coloured than ref. sol. BY5
Acidity or alcalinity	Complies
Related substances	
Impurity C	=< 0.3 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Oxalates	=< 0.35 %
Water	=< 10.0 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool and well-ventilated place, away from heat, flames, sparks and other sources of ignition.

REMARKS

Sodium Cromoglicate 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

SODIUM CROMOGLICATE is a chromogenic derivative with a stabilizing action on the mast cell membrane, which prevents the release of histamine.

It is poorly absorbed in the digestive tract, with a bioavailability of 1%. By inhalation comes 8-10% of the dose to the lungs, which is rapidly absorbed, and is excreted unchanged by urine and bile. By nasal route less than 7% is absorbed. Most of the inhaled or intranasal dose is ingested and excreted unaltered with the feces. Ophthalmic route absorbs 0.03%. The

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intravenous elimination half-life is 20-60 minutes and orally 80 minutes.
It is used for the prevention of allergic reactions, although it has no direct antihistamine action.
It can prevent the asthmatic response to different stimuli, but it has no bronchodilator action, and never used as treatment in acute asthmatic crises.
It is also used in the prophylaxis and treatment of seasonal and perennial allergic rhinitis, in allergic conjunctivitis, in the prevention of food allergies, and in mastocytosis.

Dosage
For asthma it is administered by inhaling the dry powder or a nebulized solution, at a dose of 20 mg, 4 times a day. Either equal doses of dry powder or doses of 5 mg in aerosol are usually administered before exercise.
For allergic rhinitis, approximately 2.5 - 5 mg of SODIUM CROMOGLICATE is administered in the form of a 2-4% solution administered in each nostril in the form of a nebulizer up to 6 times a day, or in a dose of 10 mg of dry powder in the form of insufflation in each nasal dosa up to 4 times a day.
For allergic conjunctivitis, ophthalmic route in drops at 2 or 4% for 4-6 times a day, or in 4% ointment for 2-3 times a day. - In food allergies and in mastocytosis, it is administered orally in doses of 200 mg in adults or 100 mg in children over 2 years, 4 times a day after meals.

Side effects
Inhalation can cause transient bronchospasm, wheezing, cough, nasal congestion, and throat irritation. Nausea, headache, drowsiness, taste alterations, pain, and joint inflammation have also been reported. Other more long-term reactions are aggravation of existing asthma, urticaria, edema, pulmonary infiltration with eosinophilia, dyspnoea, and alterations in urinary frequency.
Nasal use can cause transient irritation of the nasal mucosa, sneezing, and epistaxis.
After use in eye drops transient burning and stinging has been described.
Nausea, exanthemas, and joint pain have been reported orally.

Contraindications
Contraindicated in liver and kidney failure, acute attacks of asthma, and children under 2 years.
In allergic to dairy products, SODIUM CROMOGLICATE can trigger an allergic reaction.

Precautions
Patients treated with corticosteroids must reduce the dose of these to avoid a possible acute adrenal insufficiency.
If it is necessary to withdraw the treatment, it is advisable to gradually reduce the dose over a week.

Incompatibilities
Ionic emulsions.

Compounding examples

Cromoglicate capsules
SODIUM CROMOGLICATE - **250 mg**
for 1 capsule # 100

Notes: When formulating capsules with this active ingredient it is important to use colorless capsules to avoid possible allergic reactions, in addition to using excipients that absorb moisture, such as lactose. However, if they are capsules for inhalation, no excipients should be used.

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Cromoglicate cream
SODIUM CROMOGLICATE - **5 %**
Emulsion O / W c.s.p. - **300 g**

Modus operandi: Prepare the emulsion and remove the aqueous phase of the water bath, dissolve the SODIUM CROMOGLICATE and continue with the usual procedure for preparing emulsions.

Cromoglicate nasal solution
CROMOGLICATE SODIUM - **5 %**
Physiological serum c.s.p. - **25 mL**

Modus operandi: Dissolve the SODIUM CROMOGLICATE in the physiological saline, helping us a little from the heat of the water bath. Pack in spray bottle or spray.

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