SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cromo-COMOD nasal spray, 20 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cromo-COMOD nasal spray contains sodium cromoglicate 20 mg/ml.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray
Clear and colourless slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylactic treatment for allergic rhinitis, seasonal and perennial.

4.2 Posology and method of administration

Adults and children over 6 years old: One spray into each nostril, up to 4 times a day. The maximum daily dose should not exceed 6 sprays into each nostril. One dose corresponds to 0.14 ml (2.8 mg) of sodium cromoglicate.

4.3 Contraindications

Hypersensitivity to sodium cromoglicate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Because of the prophylactic effect, continuous treatment during a period of exposure to the allergen is important. If treatment is interrupted, symptoms of rhinitis may recur.

4.5 Interaction with other medicinal products and other forms of interaction

There are no data available. However, the occurrence of interaction with other medicinal products by simultaneous use of Cromo-COMOD nasal spray is unlikely.

4.6 Fertility, pregnancy and breastfeeding

There is insufficient data on the use of this substance in human pregnancy and breastfeeding to assess its potential harmfulness. There is so far no evidence of harmfulness in animal experiments.

4.7 Effects on ability to drive and use machines

No data are available on the effect of this product on the ability to drive and use machines. However, an effect is unlikely.

4.8 Undesirable effects

In some cases, a slight tingling of the nasal mucous membrane may occur, which will disappear after a few days.

Reporting of suspected side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

The risk that Cromo-COMOD nasal spray will cause problems in case of overdose is low.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antiallergic agents,
ATC code: R01AC01.
The active component of Cromo-COMOD nasal spray is sodium cromoglicate, which has the property of inhibiting the release of transfer substances from the so-called mast cells. This prevents a hypersensitivity reaction. Cromo-COMOD nasal spray is administered to prevent these hypersensitivity reactions. Contrary to other nasal cold and hay fever medications, it is possible that the Symptoms only disappear after 2 or 3 weeks.
Cromo-COMOD nasal spray is therefore not suitable for acute treatment.
This product contains no preservatives and is therefore also suitable for patients who have been shown to be hypersensitive to preservatives that may occur in this type of products.

5.2 Pharmacokinetic properties

Approximately 7% of the administered dose is absorbed through the nasal mucosa.
The majority of the dose is swallowed and eliminated, almost unchanged, via the gastrointestinal tract, as absorption from this is low. Systematically absorbed sodium cromoglicate is reversibly bound to plasma proteins (up to ca. 65%) and is not metabolised, but excreted unchanged in bile and urine in roughly equal proportions. The drug is rapidly cleared from plasma (in a study, plasma clearance after intravenous administration was approximately 8 ml/min/kg, and plasma elimination half-life approximately 1 hour). No accumulation occurs.

5.3 Preclinical safety data

No particulars.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol

Disodium edetate

Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date is indicated on the packaging materials.

After opening the bottle, it can be used for 12 weeks.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of Container

Package with 1 bottle filled with 15 ml solution, provided with the COMOD dosing system.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

KIVEMA LTD., 33 HACHORESH ST., KFAR SHMARYAHU 46910

8. MARKETING AUTHORISATION NUMBER

133-89-31023-00

9. MANUFACTURER

Ursaphrm Arzneimittel GmBH, Industriestrasse D-66129, Saarbrucken, Germany

Revised in May 2022 according to MoH guidelines.