SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RHINOMAXIL 100 micrograms/dose, nasal spray suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Beclometasone dipropionate ..... 100 micrograms
For one dose.
Excipient with known effect: benzalkonium chloride
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Perennial or seasonal allergic rhinitis .
Chronic inflammatory rhinitis with eosinophilia.

4.2. Posology and method of administration

Nasal route.
spray delivers 100 micrograms of beclometasone dipropionate .

Posology

Adults

The average daily dose is 400 micrograms per day, i.e., 1 spray in each nostril twice a day.
The dosage will be adapted to the patient's clinical condition and should not usually exceed 1 mg per day (i.e., 5 sprays in each nostril per day).
In chronic cases, efforts will be made to gradually reduce the doses to 200 micrograms per day, i.e., one spray in each nostril once a day.

Children over 3 years old

The average daily dose is 200 to 400 micrograms per day (6 to 13 micrograms/kg/day), i.e., 1 spray in each nostril once or twice a day.
The dosage will be adapted to the patient's clinical condition and should not usually exceed 600 micrograms in children under 12 years of age (i.e., 3 sprays in each nostril per day).
In allergic rhinitis, the initiation and duration of treatment depend on allergen exposure.
Treatment will be continued, with an effort to gradually reduce doses as soon as symptoms improve.

Method of administration

Shake the bottle vigorously before application.
Remove the cap and press 1-2 times in the air to activate.
Administer as follows:
1. Clean the nose thoroughly.
2. Remove the protective cap.
3. Remove the ring.
4. Press the sprayer several times until a fine mist is obtained.
5. Insert the nasal applicator into one nostril and close the other by pressing down with a finger. Inhale while pressing down on the base of the nasal applicator. This delivers a precise dose of the active ingredient. Repeat the same procedure in the other nostril.
6. After use, replace the ring on the bottle, as well as the cap.

When using the medication for the first time, or after a few days of not using it, remove the cap and press the sprayer several times until a fine mist is obtained.
If no mist comes out, do not try to unclog the sprayer opening with a pin or any other sharp object, but remove the nozzle by pulling it upwards and clean it by soaking it in hot water for a few minutes. Then rinse it under the tap and let it dry before reassembling it.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- Hemostasis disorders, particularly epistaxis.

- Oro -bucco-nasal and ophthalmic infection by herpes virus.

4.4. Special warnings and precautions for use

In children, in the case of prolonged treatment, it is important to remain vigilant regarding the risks of impact on growth. The risk of systemic effects, adrenal suppression and impact on growth is increased when administered concomitantly with inhaled corticosteroid therapy or, a fortiori, systemic corticosteroid therapy.
Systemic effects may occur during long-term treatment with high doses of nasal corticosteroids. However, the risk of systemic effects remains lower than with oral corticosteroids and can vary depending on individual susceptibility and the composition of the specific corticosteroid product used. Possible systemic effects include Cushing's syndrome or Cushingoid symptoms , skin thinning, subcutaneous hematomas, adrenal insufficiency, growth retardation in children and adolescents, decreased bone density, cataracts and glaucoma, and, more rarely, psychological and behavioral disorders including psychomotor hyperactivity, sleep disturbances, anxiety, depression, or aggression (particularly in children).
Visual disturbances may occur during systemic or local corticosteroid therapy. If blurred vision or any other visual symptoms develop during corticosteroid therapy, an ophthalmological examination is required to check for conditions such as cataracts, glaucoma, or rarer conditions like central serous chorioretinopathy , which have been reported with systemic and local corticosteroid administration.
The concurrent administration of nasal corticosteroids in patients receiving long-term oral corticosteroid therapy does not eliminate the need for precautions when reducing oral corticosteroid doses. These doses must be reduced very gradually, and withdrawal must be carried out under close medical supervision (monitoring for signs of acute or subacute adrenal insufficiency) that continues beyond the discontinuation of systemic corticosteroid therapy.
Local nasal administration of corticosteroids is not recommended in patients who have recently experienced nasal septum ulceration, or who have undergone surgery or trauma to the nose, until healing is complete.
This medicine contains 35.00 µg of benzalkonium chloride per dose. Benzalkonium chloride may cause irritation or swelling of the nasal mucosa, particularly with long-term use.
It is important to ensure the nasal passages are clear for optimal product diffusion. Advise the patient to clear their nose before instilling the product.
In cases of major nasal obstruction, a detailed examination of the ENT area should be performed.
In cases of pulmonary tuberculosis or pulmonary fungal infection, close monitoring and appropriate treatment are essential.
In the case of prolonged treatment, repeated examinations of the nasal mucosa are recommended (as a guideline, approximately 2 months after starting treatment and then every 6 months) to assess the potential impact of corticosteroid therapy on the nasal mucosa. If atrophy of the nasal mucosa is observed, a reduction in the dose of topical corticosteroids should be considered.
Advise the patient that this is a regular treatment, and that a delay of several days of treatment may be necessary before observing the effects on the symptoms of rhinitis.
Athletes should be aware that this product contains an active ingredient that may cause a positive result in doping tests.

4.5. Interactions with other medicinal products and other forms of interaction

Beclometasone metabolism is less dependent on CYP3A than that of some other corticosteroids, and interactions are generally unlikely; nevertheless, when used concomitantly with strong CYP3A inhibitors (e.g., ritonavir, cobicistat), the possibility of systemic effects cannot be excluded, and therefore caution and adequate monitoring are advised when using these agents.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

In animals, experimentation highlights a teratogenic effect, which varies according to the species.

In humans, epidemiological studies have not detected any malformation risk linked to taking oral corticosteroids during the first trimester.
In cases of chronic diseases requiring treatment throughout pregnancy, a slight delay in intrauterine growth is possible.
Neonatal adrenal insufficiency has been observed in rare cases following high-dose corticosteroid therapy.
It may be justified to observe a period of clinical (weight, diuresis) and biological (glycemia) monitoring of the newborn.
Consequently, this medication can be prescribed during pregnancy if needed.

Breastfeeding

beclomethasone into breast milk has not been studied. However, other corticosteroids are excreted in breast milk.
The available data seem to show good tolerance in children; however, the biological or clinical impact of long-term maternal treatment has not been evaluated to date.
Consequently, breastfeeding is possible in the case of short-term treatment. In the case of chronic treatment, breastfeeding should be avoided as a precaution.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undesirable effects

Local effects

Possible side effects include nosebleeds, nasal irritation, and dryness of the nasal mucosa.
Hypersensitivity reactions have been reported (itching, skin rashes, facial edema).
Cases of nasal and pharyngeal Candida albicans infections have been reported during treatment with topical corticosteroids. In such cases, it is preferable to discontinue nasal corticosteroid therapy and consider initiating appropriate treatment.
Rare cases of septal perforation and ocular hypertension have been reported with corticosteroids administered nasally.
Due to the presence of benzalkonium chloride, there is a risk of irritation or edema of the nasal mucosa (see section 4.4).

Systemic effects

During long-term administration of beclomethasone , systemic effects, particularly on growth in children, cannot be ruled out (see section 4.4). This risk is increased with concomitant administration of inhaled corticosteroids or, even more so, systemic corticosteroids.
The risk of latent corticotropic insufficiency after prolonged administration should be considered in the event of intercurrent infection, accident or surgical intervention.
Very rare occurrence: cataracts and glaucoma.
Frequency not known: blurred vision (see section 4.4), headaches.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals should report any suspected adverse reactions using the FRILAB reporting form available under the pharmacovigilance tab of the website: www.frilab.ch

4.9. Overdose

Prolonged overdose could lead to pituitary -adrenal suppression and, if continued, clinical signs of hypercorticism. These symptoms will disappear after discontinuation of treatment, which should be gradual.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Nasal Glucocorticoid (R: Respiratory System)
Beclometasone dipropionate administered nasally exerts an anti-inflammatory activity on the nasal mucous membranes
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5.2. Pharmacokinetic properties

Beclometasone dipropionate , partly absorbed through the nasal mucosa and partly swallowed, is metabolized in the liver into monopropionate and beclometasone alcohol , then excreted as inactive metabolites in the bile and urine.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Polysorbate 20, microcrystalline cellulose and sodium carmellose , benzalkonium chloride, phenylethyl alcohol , glucose monohydrate, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

No special storage precautions are required.

6.5. Nature and contents of container

120 and 200 doses in a 35 ml spray bottle (PET) with dosing pump and nasal tip.

6.6. Special precautions for disposal and handling

See section 4.2.

7. HOLDER, OPERATOR AND MANUFACTURERS

Owner and operator :

FRILAB SA
17, rue des Pierres du Niton 1207 Geneva
Swiss

Manufacturers :

Chiesi Farmaceutici SpA,

Via San Leonardo, 96, 43122 Parma,

Italy

ZETA Farmaceutici SpA,

Via Galvani, 10, 36066 Sandrigo (VI),

Italy

10. DATE OF REVISION OF THE TEXT

02.08.2024

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List I