Rinoclenil 100 mcg nasal spray suspension

Bottle for 200 actuations

COMPOSITION
100 ml of suspension contain:
Active ingredient: Beclometasone dipropionate 77 mg.
Excipients: polysorbate 20, microcrystalline cellulose and sodium carboxymethyl cellulose, benzalkonium chloride, phenylethyl alcohol, glucose (dextrose) monohydrate, purified water.
Each puff delivers 100 micrograms of beclometasone dipropionate.

PHARMACEUTICAL FORM AND CONTENT
Nasal spray, suspension, bottle with metering pump and nasal applicator (200 deliveries).

THERAPEUTIC CLASS
Glucocorticoid with nasal decongestive activity for topical use.

THERAPEUTIC INDICATIONS
Prophylaxis and treatment of seasonal and perennial allergic rhinitis and vasomotor rhinitis.

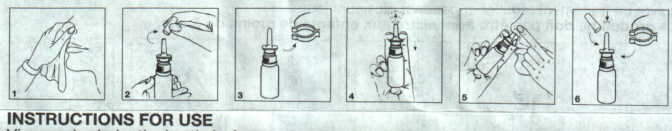
CONTRAINDICATIONS
Local viral and tubercular infections. Hypersensitivity to the active ingredient or to any excipient. Contraindicated in children aged under 6 years. Generally contraindicated in pregnancy and lactation (see special warnings).

PRECAUTIONS FOR USE
The use, especially if prolonged, of products for topical use may give rise to sensitization phenomena and exceptionally to systemic side effects typical of this drug class. In any case, it is necessary to discontinue the treatment and institute a suitable therapy.
In pediatric patients receiving prolonged treatments with nasal corticosteroids, a periodical check of their regular growth is recommended.
Though RINOCLENIL is able to control most cases of seasonal allergic rhinitis, an abnormally high allergen stimulation can require a proper supplemental therapy, especially for controlling eye symptoms.
It is necessary to take care of the patients' passage from a systemic steroidal therapy to RINOCLENIL, if there is any reason to suspect that patients' adrenal function is impaired.

INTERACTIONS
None known.

SPECIAL WARNINGS
Pregnancy and lactation. In pregnant women the product should be administered in case of real need, under direct medical control. There are insufficient data supporting the safety of use of beclometasone dipropionate during pregnancy in humans. In reproductive studies in animals, only after high systemic exposures the typical undesired side effects of potent corticosteroids were observed. However, the administration by nasal application of beclometasone dipropionate avoids the high exposure level occurring with systemic administration. The use of the product during pregnancy should be taken into consideration just when the envisaged benefits outweigh the possible risks for the fetus. The product has been widely used for several years without any apparent damages. It is reasonable to believe that beclometasone dipropionate is excreted in the milk, but with the doses used for nasal application the presence of significant concentrations in the mother milk is unlikely. However, the use of beclometasone dipropionate during lactation requires that the risk-benefit ratio be duly evaluated both for mother and baby.

POSOLOGY, METHOD AND FREQUENCY OF ADMINISTRATION
Adults and children aged over 6 years: two puffs into each nostril once a day.
In children, should it be considered as suitable, an administration scheme of fractioned doses can be maintained, with just one actuation into each nostril twice a day. The onset of action is not immediate, and for a full therapeutic benefit, a regular use is advisable for several days.
The product should not be administered to children aged under 6 years.



INSTRUCTIONS FOR USE
Vigorously shake the bottle before each administration. Moreover, before starting therapy, it is recommended to remove the protecting cap (2), protecting ring (3) and repeatedly actuate the metering pump (4) in order to start the nebulization mechanism.
Perform the actuation as follows:
1) Carefully clean the nose.
2) Remove the protecting cap.
3) Remove the side protecting ring blocking the pump.
4) Hold the bottle as illustrated in the figure. Repeatedly actuate the metering pump in order to start the nebulization mechanism, up to obtain a visible spray.
5) Lay the nasal applicator on a nostril, closing with a finger the other one. Breathe in and press at the same time the bottom of the nasal applicator as shown in the figure. In this way a single and exactly metered dose of active ingredient is delivered. Repeat the same operation in the other nostril
6) After use, close again with the protecting cap and ring.

Should the actuator become obstructed, rinse it carefully with lukewarm water, without intervening on the hole with pointed objects.

OVERDOSE
The administration of high quantities of beclometasone dipropionate during a short period of time can bring about suppression of the hypothalamus-hypophysis-adrenal axis. In this case, the dose of RINOCLENIL should be immediately reduced to the recommended dose.

UNDESIRED EFFECTS
Systemic undesired effects are extremely unlikely due to the low doses used. Nevertheless, a particular care should be paid in the prolonged use of the product, maintaining the patient under strict control in order to timely detect possible systemic effects (osteoporosis, peptic ulcer, signs of secondary adrenal failure). As for other nasal preparations, some topical burnings might appear, as well as irritation, dryness and seldom epistaxis.
Rare cases of nasal septum perforation have been reported following nasal applications with corticosteroids. Seldom cases of intraocular pressure increases or glaucoma have been associated to beclometasone dipropionate formulations for nasal applications.
In case of infection, turn to the doctor to allow a suitable therapy to be instituted.The observance of the instructions reported in the present package insert reduces the the risk of side effects. Inform your doctor or chemist about any undesired effect even if not reported in the present leaflet.

EXPIRY DATE AND STORAGE
See the expiry date printed on the package; this date should be intended for the unopened and correctly stored product. Store below 30 °C

ATTENTION: do not use the medicinal product after the expiry date indicated on the package.

Keep out of the reach of children

Approved: 4 April, 2003

chiesi

81L56/01