**CONTRAINDICATIONS (RHINOCORT Capsule is contraindicated in the following patients.)**

(1) Patients with infectious disease or systemic mycosis for which effective antimicrobial drugs are not available. [Symptoms may be exacerbated.]

(2) Patients with a history of hypersensitivity to any of the ingredients of RHINOCORT Capsule.

**RELATIVE CONTRAINDICATIONS (As a general rule, RHINOCORT Capsule is contraindicated in the following patients. If the use of this Product is considered essential, it should be administered with care.)**

Patients with tuberculous disease [Symptoms may be exacerbated.]

**DESCRIPTION**

<table>
<thead>
<tr>
<th>Brand name</th>
<th>RHINOCORT Capsule for Nasal spray 50 µg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage form</td>
<td>Capsule (for Nasal spray)</td>
</tr>
<tr>
<td>Active ingredient</td>
<td>Beclometasone Dipropionate</td>
</tr>
<tr>
<td>Content of active ingredient (per capsule)</td>
<td>50 µg</td>
</tr>
<tr>
<td>Inactive ingredient</td>
<td>Hydroxypropylcellulose, Magnesium stearate, Stearic acid</td>
</tr>
<tr>
<td>Color/ description</td>
<td>No.2 hard capsule, consists of a white body and a blue cap, contains white to yellowish white powder. The powder is almost odorless and tasteless.</td>
</tr>
</tbody>
</table>

**Appearance**

- 6.50mm
- Weight: Approx. 95 mg
- Identification code: TJN 883

**INDICATIONS**

Allergic rhinitis and vasomotor rhinitis

**DOSAGE AND ADMINISTRATION**

Usually, one capsule (50 µg of beclometasone dipropionate) each is sprayed into the nasal cavity, with a compact spray device, twice daily, i.e. in the morning (on awakening) and in the evening (at bedtime). The dose may be adjusted according to the patient’s symptoms.

**PRECAUTIONS**

1. **Careful Administration (RHINOCORT Capsule should be administered with care in the following patients.)**

   (1) Patients with infection [Symptoms may be exacerbated.]

   (2) Patients with recurrent nosebleeds [Bleeding may be intensified.]

   (3) Patients with hypertension [Blood pressure may be elevated.]

   (4) Patients with diabetes mellitus [Symptoms may be exacerbated.]

2. **Important Precautions**

   (1) As a general rule, RHINOCORT Capsule should not be used in status asthmaticus or in sudden exacerbations of asthma.
(2) In patients with severe hypertrophic rhinitis or nasal polyps, concomitant treatment for reducing the symptoms to some extent is recommended in order to ensure the effect of RHINOCORT Capsule in the nasal cavity.

(3) If nasal symptoms are exacerbated during administration of RHINOCORT Capsule, antihistaminic drugs or systemic steroids should be used concomitantly for a short period, and the dose of the concomitant drug should gradually be reduced as the symptoms become milder.

(4) Since RHINOCORT Capsule has prolonged effects, especially in a long-term administration in the patients of perennial rhinitis, an effort should be made to reduce the dose or suspend administration of this Product when symptom improvement is maintained.

(5) Dose reduction of systemic steroids should be conducted gradually in response to the symptom stabilization after the start of inhaling RHINOCORT Capsule. The dose reduction should be conducted according to the usual dose-reducing procedure for steroids.

(6) Since adrenocortical insufficiency is suspected in patients on long-term or massive systemic steroid therapy, adrenocortical function should be monitored during dose reduction or after withdrawal of systemic steroids, and attention should be paid to such stresses as injuries, surgeries, and severe infections. If necessary, the dose of systemic steroids should be temporarily increased.

(7) Dose reduction and withdrawal of systemic steroids may be associated with the occurrence or exacerbation of bronchial asthma, and occasionally such symptoms as eczema, urticaria, dizziness, palpitation, malaise, hot flushes facial, and conjunctivitis. (Appropriate measures should be taken when such symptoms are noted.)

3. Adverse Reactions

Eleven (11) adverse drug reactions were observed in 11 (2.6%) of 420 patients evaluated for safety at the time of approval. The major adverse reactions were nasal symptoms, including 2 events of nasal cavity irritation (0.5%), 1 event of nasal cavity foreign body feeling (0.2%), 1 event of sensation of nasal congestion (0.2%), 1 event of dysosmia (0.2%), etc. Change in laboratory test result considered as adverse reaction was 1 event of serum cortisol increased (0.2%).

(1) Clinically significant adverse reactions

Eyes: Intraocular pressure increased and glaucoma have been reported outside Japan. Appropriate measures, such as discontinuation of use, should be taken if such symptoms are noted.

(2) Other adverse reactions

<table>
<thead>
<tr>
<th>Type/Incidence</th>
<th>Incidence unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity</td>
<td></td>
</tr>
<tr>
<td>Note 1</td>
<td></td>
</tr>
<tr>
<td>Nasal cavity</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
</tr>
<tr>
<td>Psychoneurosis</td>
<td></td>
</tr>
</tbody>
</table>

Note 1) Appropriate measures, e.g. discontinuation of administration, should be taken if such adverse drug reactions are noted.

Note 2) According to the spontaneous reports and/or reports on other beclometasone dipropionate preparations.

Note 3) Frequency of inhalation should be decreased or inhalation should be discontinued.

4. Use in the Elderly

Since elderly often have reduced physiological functions, RHINOCORT Capsule should be used with caution while monitoring the patient’s condition and paying attention to the duration of administration, etc.

5. Use during Pregnancy, Delivery or Lactation

RHINOCORT Capsule should be used to pregnant or possibly pregnant women only if the expected therapeutic benefits outweigh the possible risks associated with treatment. [Teratogenicity has been reported in animal experiments.]

6. Pediatric Use

(1) Since RHINOCORT Capsule is a steroid preparation, it should be used only when remission of symptoms cannot be achieved with nonsteroidal drugs.

(2) Use over a prolonged period or in large amounts may lead to impairment of growth. When RHINOCORT Capsule is used, instructions for proper use should be given and the clinical course should be carefully monitored.

(3) Due to the difficulty of spray device manipulation or inhalation, there has been no experience with use in low birth weight infants, newborns, infants, or children 5 years of age or younger.

7. Overdosage

Overdosage may result in suppression of pituitary-adrenal system function. When the suppression persists over a prolonged period, symptoms similar to those observed after systemic administration of adrenocortical steroids may appear. In such cases, the dose of RHINOCORT Capsule should be gradually reduced by the same procedure as for discontinuation of systemic steroids.
8. Precautions Concerning Use

(1) Route of administration
1) RHINOCORT Capsule is an adhesive powder (external preparation) to be sprayed onto the nasal cavity mucosa. The capsules must not be taken orally.
2) Never inhale RHINOCORT Capsule to treat bronchial asthma.
3) Never spray RHINOCORT Capsule onto the eyes.

(2) Method of administration
RHINOCORT Capsule should be inhaled into the nasal cavity by using a compact spray device (Puvlizer®), which is exclusively made for its use, according to the illustration inserted in the case.

(3) For administration
If patients have a large amount of nasal discharge, they should be advised to blow their nose, and then spray RHINOCORT Capsule and inhale it.

(4) Precautions regarding dispensing
For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to use. (It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as mediastinitis.)

9. Other Precautions
Nasal congestion may occur as an adverse reaction to such antihypertensive drugs as reserpine-type agents and α-methyldopa preparations. When RHINOCORT Capsule is administered to patients with allergic rhinitis or vasomotor rhinitis taking such antihypertensive drugs, the effect of this Product on the symptoms of nasal congestion may be masked. Therefore, RHINOCORT Capsule should be administered with careful clinical observation.

PHARMACOLOGY

1. Anti-inflammatory action
In the vasoconstriction study in human skin, beclometasone dipropionate exhibited a local anti-inflammatory action approximately 5 times stronger than that of triamcinolone acetonide and approximately 600 times stronger than that of dexamethasone.

2. Prevention against challenge reactions
A quantitative nasal mucosal challenge test was performed using house dust antigen in adult patients with perennial nasal allergy, and changes in nasal respiratory resistance were investigated during repeated administration of 3μg/day, 25μg/day, 50μg/day and 100μg/day of beclometasone dipropionate for one week. The results revealed dose-dependent decrease of both the susceptibility and reactivity of the nasal mucosa to the antigen, showing preventive inhibition of nasal respiratory resistance induced by nasal mucosal challenge. The inhibitory effect coincided with the effect in improving the clinical nasal symptoms (sneezing, rhinorrhea, and nasal congestion).

PHYSICOCHEMISTRY

Nonproprietary name: Beclometasone Dipropionate
Chemical name:
9-Chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17, 21-dipropanoate
Structural formula:

![Structural formula image]

Molecular formula: C₃₀H₃₇ClO₇
Molecular weight: 521.04
Melting point: approximately 208°C (with decomposition)
Description: Beclometasone dipropionate occurs as white to pale yellow powder. It is odorless. It is freely soluble in chloroform, soluble in methanol, sparingly soluble in ethanol (95%) and in 1,4-dioxane, slightly soluble in diethyl ether, and practically insoluble in water.
PRECAUTIONS FOR HANDLING

Storage:
(1) Patients should be advised to be careful of moisture absorption once the capsules are removed out from the PTP package.
(2) The color of the capsules may fade slightly as a result of exposure to room light, but it has no effect on the content.

PACKAGING
PTP: 100 capsules (10 capsules x 10)
500 capsules (10 capsules x 50)

REFERENCES
   75, 1984.
4) Okamoto M., et al.: Oto-rhino-laryngology, 27(Suppl 2)
   613, 1984.

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