

## Section 3 - Summary of Product Characteristics

### Product Summary

**1. Trade Name of the Medicinal Product**

Beclorhino Allergy 50 microgram Aqueous Nasal Spray Suspension

**2. Qualitative and Quantitative Composition**

Beclomethasone Dipropionate Ph.Eur.50 micrograms per spray.  
For Excipients see 6.1

**3. Pharmaceutical Form**

Nasal spray suspension

A glass vial fitted with a metered pump and nasal tip containing an opaque white nasal spray suspension.

### Clinical Particulars

**4.1. Therapeutic Indications**

For the prevention and treatment of seasonal allergic rhinitis.

**4.2. Posology and Method of Administration**

1 Spray = 50µg beclomethasone dipropionate  
For administration by the intra-nasal route.

Adults and the elderly: Two sprays into each nostril twice daily = 400µg/day.

In some patients, a preferred dosage may be one spray into each nostril three or four times daily.

The total daily dose should not exceed eight sprays.

For maximum therapeutic benefit regular use is essential. Maximum benefit may not be obtained in the first few doses, and the co-operation of patients is required to ensure compliance with a regular dosage schedule.

For use in patients aged 18 years and over.

**4.3. Contra-indications**

Patients with a known hypersensitivity to any of the ingredients.

**4.4. Special Warnings and Precautions for Use**

Beclomethasone Aqueous Nasal Allergy Spray is not specifically contra-indicated in the presence of infections of the nasal passages or paranasal sinuses, but these infections should be treated appropriately. When patients are transferred from systemic steroid therapy to Beclomethasone aqueous nasal spray, care should be exercised if there is a suspicion that the adrenal function is impaired.

Systemic effects may occur rarely. These effects include hypothalamic-pituitary-adrenal suppression and growth retardation in children.

Beclomethasone aqueous nasal allergy spray will control seasonal allergic rhinitis for most patients, but, if there is an abnormal heavy challenge by summer allergens, in some patients it may be necessary to give additional treatment, particularly to control eye problems.

#### **4.5. Interactions with other Medicaments and other forms of Interaction**

None stated.

#### **4.6. Pregnancy and Lactation**

##### Pregnancy

There is inadequate evidence of safety in human pregnancy. In animals the administration of corticosteroids to pregnant animals can cause foetal abnormalities including cleft palate and growth retardation. There is a small risk that such effects could occur to the human foetus. However, the animal effects occurred after relatively high systemic dosage: whereas, direct application intra-nasally provides minimal systemic absorption.

If Beclomethasone aqueous nasal spray is used in pregnancy, the risk to benefit ratio must be assessed against possible hazards. It should be noted that beclomethasone dipropionate has been in widespread use for many years without apparent ill-effects.

##### Lactation

Although no specific studies have been undertaken regarding the transfer of beclomethasone dipropionate into milk of lactating animals, it can be assumed that it is secreted in milk. However, there is low potential for significant levels in human milk following direct intra-nasal use of beclomethasone dipropionate.

If Beclomethasone aqueous nasal spray is used in breast feeding mothers, the therapeutic benefits should be weighed against the possible hazards to mother and baby.

#### **4.7. Effects on Ability to Drive and Use Machines**

None stated

#### **4.8. Undesirable Effects**

Rare cases of nasal septal perforation have occurred. Dryness and irritation of the nose and throat, an unpleasant taste and smell, and epistaxis have occurred rarely (as with the use of nasal sprays). There have been rare cases of raised intra-ocular pressure and glaucoma.

#### **4.9. Overdose**

The only harmful effect of inhalation of large amounts of beclomethasone dipropionate in a short period of time is suppression of the hypothalamic-pituitary-adrenal function. No special emergency treatment is required. Treatment with Beclo-Rhino should be continued at the prescribed (recommended) dose because the hypothalamic-pituitary-adrenal function recovers in a day or two.

### **Pharmacological Properties**

#### **5.1. Pharmacodynamic Properties**

-Local steroidal anti-inflammatory agent

-Beclomethasone dipropionate exerts marked anti-inflammatory activity on the skin and nasal mucosa.

The slowing effect on the hypothalamic-pituitary-adrenal axis following administration via the nasal route is evident only at doses equal to or greater than 8mg whilst the local therapeutic effect is obvious at the mean dose of 400µg per day in adults. The difference between these dose levels and the metabolic inactivation of this product accounts for the lack of general side effects at the recommended daily dosage.

**5.2. Pharmacokinetic Properties**

Beclomethasone dipropionate is very slightly absorbed by the nasal mucosa. It is metabolised into monopropionate and beclomethasone - alcohol in the liver, then excreted as inactive metabolites in bile and urine.

**5.3. Preclinical Safety Data**

None stated

**Pharmaceutical Particulars**

**6.1. List of Excipients**

Glucose Monohydrate  
Microcrystalline cellulose USP/Sodium carboxymethyl cellulose  
Phenylethyl alcohol  
Polysorbate 80  
Benzalkonium chloride  
Water for injection

**6.2. Incompatibilities**

Not applicable

**6.3. Shelf Life**

As packed for sale 24 months  
After first opening 3 months

**6.4. Special Precautions for Storage**

Do not store above 25°C. Do not refrigerate or freeze. Keep the container in the outer carton.

**6.5. Nature and Contents of Container**

Glass type & colour: Type III amber glass  
15 ml glass spray bottle (100 spray)  
with metered pump and nasal tip

**6.6. Instruction for Use/Handling**

No special requirements

**Administrative Data**

**7. Marketing Authorisation Holder**

Goldshield Pharmaceuticals Ltd

NLA Tower  
Croydon CRO OXT  
United Kingdom

- 8. Marketing Authorisation Number**  
899/17/2
- 9. Date of First Authorisation/Renewal of Authorisation**
- 10. Date of Revision of the Text**  
May 2006.