Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Beclo-Rhino 50 microgram Aqueous Nasal Spray Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Beclomethasone Dipropionate 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.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prophylaxis and treatment of perennial and seasonal allergic rhinitis, including hay fever and vasomotor rhinitis.
Inflammatory rhinitis, especially eosinophil-induced rhinitis.

4.2 Posology and method of administration

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

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

Children: (over 6 years). As for adults and the elderly. Use by children under 6 years of age is not recommended because of insufficient clinical data.

4.3 Contraindications

Patients with a known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Beclomethasone Aqueous Nasal 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 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 Interaction with other medicinal products 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 Beclomethasone dipropionate should be continued at the prescribed (recommended) dose because the hypothalamic pituitary-adrenal function recovers in a day or two.

5 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 8 mg whilst the local therapeutic effect is obvious at the mean dose of 400mcg 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose Monohydrate
Microcrystalline cellulose
Sodium Carboxymethyl Cellulose
Phenylethyl alcohol
Polysorbate 80
Benzalkonium chloride
Water for Injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

As packaged 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

15 ml Type III amber glass spray bottle (100 spray).
27 ml Type III amber glass spray bottle (200 spray).

Both with metered pump and nasal tip.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd
NLA Tower
Croydon CR0 0XT
England

8 MARKETING AUTHORISATION NUMBER

PA 899/17/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 14 May 2004

10 DATE OF REVISION OF THE TEXT

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