IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0899/017/002
Case No: 1025955

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Goldshield Pharmaceuticals Ltd

NLA Tower, **12-16 Addiscombe Road,Croydon**, **Surrey CRO 0XT**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Beclo-Rhino Allergy 50 microgram Aqueous Nasal Spray Suspension

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **10/11/2006** until **09/11/2011**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Beclo-Rhino Allergy 50 microgram Aqueous Nasal Spray Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Beclometasone Dipropionate 50 micrograms per spray.

For full list of Excipients see section 6.1.

3 PHARMACEUTICAL FORM

Nasal Spray, Suspension.
A glass vial fitted with a metering pump and nasal tip containing an opaque white nasal spray suspension.

4 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 beclometasone 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 Contraindications

Patients with a known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Beclometasone 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 Beclometasone 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.

Beclometasone 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 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 coricosteroids 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 Beclometasone aqueous nasal spray is used in pregnancy, the risk to benefit ratio must be assessed against possible hazards. It should be noted that beclometasone 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 beclometasone 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 beclometasone dipropionate.

If Beclometasone 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 beclometasone 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-pituitaryl-adrenal function recovers in a day or two.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Local steroidal anti-inflammatory agent
Beclometasone 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

Beclometasone 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 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 vial (100 spray)
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, 12 - 16 Addiscombe Road
Croydon CRO OXT
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 899/17/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of Frst Authorisation: 10th November 2006

10 DATE OF REVISION OF THE TEXT