SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hayfever & Allergy Relief 50 micrograms/dose Nasal Spray

Boots Hayfever & Allergy Relief 50 micrograms/dose Nasal Spray Numark Hayfever Relief 50 microgram Nasal Spray

Pollenase Allergy Relief 50 micrograms / dose Nasal Spray

Tesco Allergy Relief 50 micrograms/dose Nasal Spray

Lloyds Pharmacy Hayfever Relief 50 micrograms/dose Nasal Spray Asda Hayfever Relief 50 micrograms /dose Nasal Spray

Careway Hayfever Relief 50 micrograms /dose Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each spray contains: Beclometasone Dipropionate 50 micrograms

Excipient(s) with known effect:

Benzalkonium chloride: 0.023mg per spray

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Mechanical driven (atomising) spray for nasal use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

7 Hayfever Relief Spray is indicated for the treatment and prevention of allergic rhinitis including hayfever in adults aged 18 years and over. The drug has a potent anti-inflammatory effect within the respiratory tract.

4.2 Posology and method of administration

Hayfever Relief Spray for intranasal administration only.

The minimum effective dose according to individual response should be used at which the control of symptoms is maintained (200 to 400 micrograms/day), This nasal spray is not recommended for children or adolescents under 18 years of age.

A dosage regimen of two sprays into each nostril morning and evening is recommended. The maximum number of sprays that should be administered each day is 8. Once the symptoms are under control the dosage may be reduced to one spray into each nostril twice a day.

If symptoms have not improved within 14 days, consult your doctor or pharmacist. For full therapeutic benefit, regular use is essential. The co-operation of the patient should be sought to comply with the regular dosage schedule and it should be explained that the maximum relief may not be obtained within the first few doses..

If a dose is missed, then the next dose should be taken when it is due.

4.3 Contraindications

Hayfever Relief Spray is contra-indicated in patients with a history of hyper-sensitivity to any of the components.

4.4 Special warnings and precautions for use

Nasal passage infections and paranasal sinuses should be appropriately treated. Hayfever Relief Spray may be used in conjunction with other medicaments if required.

Medical advice should be sought before using Hayfever Relief 50 micrograms / dose Nasal Spray by patients using other forms of corticosteroid treatments such as asthma medications, tablets, injections, similar nasal sprays, eye or nose drops, creams or ointments.

Caution should be exercised whilst transferring patients from systemic steroid treatment to Hayfever Relief Spray if there is doubt that their adrenal function is impaired.

Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

Hayfever Relief Spray will control seasonal allergic rhinitis in most cases. However, an abnormally heavy challenge of summer allergies, may in certain situations, necessitate appropriate additional therapy, especially to control eye symptoms.

Systemic effects of nasal corticosteroids may occur particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses. It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for *higher than recommended* doses being used then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Hayfever Relief Spray contains benzalkonium chloride which may cause irritation or swelling inside the nose especially if used for a long time.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

4.6 Fertility, Pregnancy and lactation

The use of Beclometasone Dipropionate in pregnancy requires that the benefits of the drug be weighed against the possible hazards. It should be noted that the drug has been in widespread use for many years without apparent ill consequence.

Safety in pregnancy has not been established. Corticosteroid administration to pregnant animals can cause abnormalities of foetal development including cleft palate and intra uterine growth retardation. Therefore there may be a very small risk of such effects in the human foetus.

Lactation:

The use of Beclometasone Dipropionate in mothers breast-feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother and baby.

No specific studies examining the transference of Beclometasone Dipropionate into the milk of lactating animals have been performed. It is reasonable to assume that Beclometasone Dipropionate is secreted in milk, but at the dosages used for direct intranasal administration there is low potential for significant levels in breast milk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. Such effects may include hypothalmic-pituitary-adrenal (HPA) suppression and growth retardation in children.

Rare cases of nasal septal perforation have been reported following the use of intranasal corticosteroids.

Rare cases of raised intra-ocular pressure or glaucoma or blurred vision (see section 4.4) have been reported.

As with other nasal sprays, dryness and irritation of the nose and throat, unpleasant taste and smell and epistaxis have been reported rarely.

Very rare cases of hypersensitivity reactions including rashes, urticaria, pruritus and erythema and oedema of the eyes, face, lips and throat, anaphylactoid / anaphylactic reactions, dyspnoea and / or Bronchospasm have been reported

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

The only harmful effect that follows inhalation of large amounts of the drug over a short time period is suppression of the hypothalmic-pituitary-adrenal (HPA) function. No special emergency action need be taken. Treatment with a Hayfever Relief Spray should be continued at the recommended dose. HPA function reverses in one or two days.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R01AD01

Beclometasone Dipropionate is a glucocorticoid. It is a synthetic corticosteroid esterified at the 17 position and is more potent topically than systemically. This drug is currently only used topically for it's anti-inflammatory activity. In addition to the local anti-inflammatory action it exerts it also has immunosuppressive activity. There are a number of factors contributing to the mechanisms behind these actions. Firstly and foremost the drug inhibits the adherence of neutrophils and monocyte-

macrophages to the capillary endothelial cells of the inflamed area. Secondly it obstructs the effect of macrophage migration inhibitory factor. Finally, Beclometasone Dipropionate also decreases the activation of plasminogen to plasmin and by inhibition of phospholipase A_2 activity, it reduces the formation of prostaglandins and leukotrienes in the local tissue. (SPC pharmacokinetics).

5.2 Pharmacokinetic properties

The greater part of any drug administered by inhalation is ultimately swallowed after being deposited in the mouth and oro-pharnyx. It has been shown that when 4mg Beclometasone Dipropionate was administered to man as a microfine suspension over 90% of the drug was absorbed. The rate of absorption is slow, peak serum levels being attained at about 3 to 5 hours after administration.

Beclometasone Dipropionate is widely distributed in the body tissues. It is found in the liver, in the kidney and in white blood cells. It is 87 per cent bound to human plasma protein (cortisol binds 90%).

Beclometasone Dipropionate is hydrolysed after oral administration by tissue and faecal esterases in vitro. It is therefore probable that the Beclometasone Monopropionate and Beclometasone present in faeces after oral administration result from hydrolysis of unabsorbed drug by gut esterases, and that the polar metabolites found in human faeces probably arise from the biliary excretion of metabolites of absorbed drug.

5.3 Preclinical safety data

No data are available on the toxic effects of Beclometasone Dipropionate but these are likely to be similar to toxic effects reported for other halogenated topical corticosteroids. Toxic effects of corticosteroids in acute toxicity studies in mouse and rat include reduction in adrenal weight, liver changes, lung consolidation and gastrointestinal effects. These are dose related, the more potent the topical steroid the greater the effect; there is no evidence to suggest that these findings have any clinical relevance in man.

Potential carcinogenic effects have been found in mice following prolonged topical application of potent corticosteroids, but there is no evidence for carcinogenicity occurring in man. No data for Beclometasone are available. Halogenated topical corticosteroids have been found to be teratogenic in mice but the relevance of this in man is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrose Anhydrous.
Polysorbate 80
Dispersible Cellulose
Benzalkonium Chloride 95%
Phenylethanol
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years - unopened

3 months - opened

6.4 Special precautions for storage

Store below 25°C. Do not refrigerate. Protect from light.

6.5 Nature and contents of container

Hayfever Relief Spray is supplied in a white plastic (high density polyethylene) bottle fitted with a screw on pump covered by a dustcap. The bottle provides 200 sprays.

6.6 Special precautions for disposal

Method of Administration

1. Remove the dust cap. Shake the bottle gently
2. On first using the nasal spray, prepare for use by pressing down on the white collar using both your index and middle fingers. Keep the base supported with

your thumb. Continue to press down until the collar stops and then allow it to return to it's original position. Repeat this action until a fine spray appears. The first five attempts to produce a spray should be allowed to go to waste. Now the spray is ready to use.

3. To use the spray, first blow your nose gently. Closing one nostril off bend your head forward slightly. Hold the bottle upright and carefully insert the applicator into the other nostril.
4. Slowly begin to breathe in through your nose and whilst doing so press down firmly on the white collar to produce a fine spray inside your nose. Breath out through your mouth.
5. Repeat steps 3 and 4 to squirt a second spray in the same nostril. Wash the nozzle frequently with warm water. This will prevent it from getting blocked. If the pump has not been used for a short period of time, re-priming may be necessary (see step 2 above).

7 MARKETING AUTHORISATION HOLDER

Merel Pharma Limited
34 Market Street,
Hyde,
SK14 1AH,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 60884/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 July 2003

10 DATE OF REVISION OF THE TEXT

14/11/2025