Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Beconase Hayfever nasal spray 50 micrograms per spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mg spray contains beclometasone dipropionate monohydrate equivalent to 50 micrograms Beclometasone Dipropionate Ph.Eur.

Excipients with known effect:
Each 100 mg spray contains benzalkonium chloride solution equivalent to benzalkonium chloride 20 micrograms.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension
An aqueous white opaque suspension in a plastic bottle fitted with a metering atomising pump and nasal applicator.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Beconase Hayfever is indicated for the prevention and treatment of allergic rhinitis, including hayfever, in adults aged 18 and over.

4.2 Posology and method of administration

Posology

Indication	Age group	Dose	Duration
Prevention and treatment of nasal congestion symptoms due to hayfever and other seasonal allergic conditions	Adults	Two intranasal applications into each nostril twice daily*	14 days**

*Total daily administration should not exceed 8 intranasal applications (400mcg/day).
Once symptoms are controlled, the dose can be reduced to 1 spray into each nostril 2 times a day (100 micrograms per day in each nostril). The dose should be titrated down to the lowest effective dose.
**If there is no response after 14 days of treatment, medical advice should be sought.
Do not use continuously for longer than 3 months without consulting your doctor.

Paediatric population:
Not recommended in children and adolescents under the age of 18.

Regular usage is essential for full therapeutic benefit. Beconase Hayfever quickly starts to bring relief and reduce swelling in the nose although it may take a few days to build up to its maximum effect.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Infections of the nasal passages and paranasal sinuses should be appropriately treated but Beconase Hayfever therapy need not be stopped.

Care must be taken while transferring patients from systemic steroid treatment to Beconase Hayfever if there is any reason to suppose that their adrenal function is impaired.

Systemic effects including reduction in growth velocity may rarely occur with excessive use of the product.

Although Beconase Hayfever will control seasonal allergic rhinitis in most cases, additional therapy may be needed to control eye symptoms in the presence of abnormally heavy allergen challenges.

Medical advice should be sought before using Beconase Hayfever in the case of recent injury or surgery to the nose, or problems with ulceration in the nose.

This medicine contains 20 micrograms benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Visual disturbances

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 interactions

Beclomethasone 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.

Paediatric population
Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

There is inadequate evidence of safety of beclometasone dipropionate in human pregnancy. In animal reproduction studies adverse effects typical of potent corticosteroids are only seen at high systemic exposure levels; direct intranasal application ensures minimal systemic exposure.

Breast-feeding

No specific studies examining the transference of beclomethasone 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 application, there is low potential for significant levels in breast milk. 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.

Fertility

There are no data available regarding the influence of Beconase Hayfever on fertility.

4.7 Effects on ability to drive and use machines

Beconase Hayfever has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (21/10), common (21/100 and <1/10), uncommon (21/1000 and <1/100), rare (21/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data. In assigning adverse events frequencies, the background rates in placebo groups were taken into account, since these rates were generally comparable to those in the active treatment group.

Body System Class	**Undesirable Effect**	**Frequency**	**Comments**
Immune system disorders	Hypersensitive reactions including rashes, urticaria, pruritis, erythema and oedema of the eyes, face, lips and throat, anaphylactoid/anaphylactic reactions, bronchospasm.	Very rare	
Nervous system disorders	Unpleasant taste, unpleasant smell.	Common	As with other nasal sprays, unpleasant taste and smells have been reported.
Eye disorders	Glaucoma, raised intraocular pressure and cataract.	Very rare	
Respiratory, thoracic and mediastinal disorders	Epistaxis, nasal dryness, nasal irritation, throat dryness, throat irritation. Nasal septal perforation.	Common Very rare	As with other nasal sprays, dryness and irritation of the nose and throat, and epistaxis have been reported. Nasal septal perforation has also been reported following the use of intranasal corticosteroids.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms and signs
The only harmful effect that follows inhalation of larger amounts of the drug over a short period is suppression of hypothalamic-pituitary-adrenal (HPA) function.

Management
No special emergency action need be taken. Treatment with Beconase Hayfever should be continued at the recommended dose. HPA function recovers in a day or two.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal preparations, corticosteroids. ATC code: R01AD01

Following topical administration beclomethasone 17,21-dipropionate (BDP) produces potent anti-inflammatory and vaso-constrictor effects.

BDP is a pro-drug with weak glucocorticoid receptor binding affinity. It is hydrolysed via esterase enzymes to the active metabolite beclomethasone-17-monopropionate (B-17-MP), which has high topical anti-inflammatory activity.

Beclomethasone dipropionate offers a preventative background treatment for hayfever when taken prior to allergen challenge. After which with regular use, BDP can continue to prevent allergy symptoms from re-appearing by reducing the sensitivity of nasal membranes.

Clinical studies carried out on patients with allergic rhinitis showed efficacy in nose symptoms, more specifically sneezing, rhinorrhea, itchy nose, and nasal congestion.

Clinical data suggests that BDP improves ocular symptoms associated with allergic rhinitis. In a 6 week randomized, double-blind, parallel study involving 44 patients treated with BDP, there was a statistically significant improvement in mean ocular symptom scores ($p<0.01$) after the 15-day study period.

BDP seems to provide relief from sinus discomfort associated with allergic rhinitis by preventing nasal obstruction, which allows a better drainage of sinuses subsequently. The precise mechanism of action is not known.

5.2 Pharmacokinetic properties

Absorption

Following intranasal administration of BDP, the systemic absorption was assessed by measuring the plasma concentrations of its active metabolite B-17-MP, for which the absolute bioavailability following intranasal administration is 44%

Following oral administration of BDP the systemic absorption was also assessed by measuring the plasma concentration of its active metabolite B-17-MP, for which the absolute bioavailability following oral administration is 41%

Distribution

The tissue distribution at steady-state for BDP is moderate (201) but more extensive for B-17-MP (4241). Plasma protein binding is moderately high (87%).

Biotransformation

BDP is cleared very rapidly from the circulation and plasma concentrations are undetectable (<50 pg/ml) following oral or intranasal dosing. Metabolism is meditated via esterase enzymes found in most tissues. The main product of metabolism is the active metabolite (B-17-MP). Minor inactive metabolites, beclometasone-21-monopropionate (B-21-MP) and beclometasone (BOH), are also formed but these contribute little to systemic exposure.

Elimination

The elimination of BDP and B-17-MP are characterised by high plasma clearance (150 and 120 l/h) with corresponding terminal elimination half-lives of 0.5h and 2.7h. Following oral admininstration of trititated BDP, approximately 60% of the dose was

excreted in the faeces within 96 hours mainly as free and conjugated polar metabolites. Approximately 12% of the dose was excreted as free and conjugated polar metabolites in the urine. The renal clearance of BDP and its metabolites is negligible.

5.3 Preclinical safety data

No data included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Carboxymethylcellulose sodium
Glucose anhydrous
Polysorbate 80
Purified water
Benzalkonium chloride
Phenylethyl alcohol

6.2 Incompatibilities

None reported.

6.3 Shelf life

30 months.
Discard three months after first using the spray.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.
Keep container in outer carton in order to protect from light.

6.5 Nature and contents of container

Beconase Hayfever is supplied in a plastic bottle fitted with a metering, atomising pump and nasal applicator. Each 20ml polypropylene container provides approximately 100 metered sprays. Each 30ml polypropylene container provides approximately 180 metered sprays.

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

Your Beconase Hayfever spray has a dust cap which protects the nozzle and keeps it clean.
Remember to take it off before using the spray (Picture 1).

A new spray, or one which has not been used for a few days, may not work the first time. You may need to "prime" the bottle by pumping the spray a few times until a fine mist is produced. To do this hold the bottle as shown. Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle.

Keeping your thumb still, press down with your fingers to pump the spray (Picture 2). Hold the nozzle pointing away from you while you are doing this.

If the spray still doesn't work and you think it may be blocked, clean it as described below.
NEVER try to unlock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

Using the spray:

1. Shake the bottle and remove the dust cap.
2. Blow your nose gently.
3. Close one nostril as shown and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown (Picture 3).
4. Start to breathe in slowly through your nose. WHILE YOU ARE BREATHING IN squirt a spray of fine mist into your nostril by pressing down firmly on the collar with your fingers (Picture 4).
5. Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through your mouth.
7. Repeat steps 3 to 6 for the other nostril.

AFTER USING THE SPRAY WIPE THE NOZZLE CAREFULLY WITH A CLEAN TISSUE OR HANDKERCHIEF, AND REPLACE THE DUST CAP.

To clean the spray:

1. Take the dust cap off.
2. Pull upwards on the white collar to remove the nozzle.
3. Soak the nozzle and dust cap in warm water for a few minutes, and then rinse under a running tap.
4. Shake off the excess water and allow to dry in a warm, NOT HOT, place.
5. Re-fit the nozzle.
6. "Prime" the bottle if necessary by pumping the spray a few times until a fine mist is produced.

YOUR NASAL SPRAY SHOULD BE CLEANED AT LEAST ONCE A WEEK, OR MORE OFTEN IF IT GETS BLOCKED.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 September 1999

Date of last renewal: 17 September 2009

10 DATE OF REVISION OF THE TEXT

December 2020