SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beconase Allergy
Beconase Hayfever

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

50 Micrograms Beclometasone Dipropionate BP per 100mg actuation.

Excipient with known effect:
Benzalkonium chloride: 20 Micrograms per 100mg actuation.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Aqueous Nasal Spray

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Beconase Allergy / Hayfever is indicated for the prevention and treatment of allergic rhinitis, including hayfever, in adults aged 18 and over. Beconase Allergy/Hayfever provides symptomatic relief from nasal congestion, runny nose, sneezing, itchy nose, eye symptoms (such as itching, watering, redness) and associated sinus discomfort.

4.2 Posology and Method of Administration

Posology

Adults aged 18 and over: The recommended dosage is two sprays into each nostril morning and evening (400 micrograms/day). Once control has been established, it may be possible to maintain control with fewer sprays. A

dosage regimen of one spray into each nostril morning and evening has been shown to be efficacious in some patients. However, should the symptoms recur, patients should revert to the recommended dosage of two sprays into each nostril morning and evening. The minimum dose should be used at which effective control of symptoms is maintained. Total daily administration should not exceed eight sprays (400 micrograms).

Beconase Allergy / Hayfever quickly starts to reduce inflammation and swelling in the nose. But for best effect patients should start to use Beconase Allergy / Hayfever two or three days before they expect to get symptoms to prevent them from developing. For full therapeutic benefit Beconase Allergy / Hayfever should be used regularly.

If symptoms have not improved after 14 days treatment, medical advice must be sought.

Beconase Allergy / Hayfever is not recommended for children or adolescents under 18 years of age.

Method of Administration
Beconase Allergy / Hayfever is for administration by the intranasal route only.

4.3 Contraindications

Beconase Allergy / Hayfever is contra-indicated in patients with a history of hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Systemic effects of nasal corticosteroids may occur, particularly at high doses when used 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).

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.

This product should not be used continuously for longer than 3 months without consulting a doctor.

Infections of the nasal passages and paranasal sinuses should be appropriately treated but do not constitute a specific contra-indication to treatment with Beconase Allergy / Hayfever.

Although Beconase Allergy / Hayfever will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may, in certain instances, necessitate appropriate additional therapy particularly to control eye symptoms.

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

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.

Excipients

Beconase Allergy/Hayfever contains Benzalkonium Chloride which may cause irritation or swelling inside the nose, especially if used for a long time.
Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6. Fertility, Pregnancy and Lactation

Fertility
No known effect.

Pregnancy
There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human fetus. It should be noted, however, that the fetal changes in animals occur after relatively high systemic exposure. Beconase Allergy / Hayfever delivers beclometasone dipropionate directly to the nasal mucosa and so minimises systemic exposure.

The use of beclometasone dipropionate should be avoided during pregnancy unless thought essential by the doctor.

Breast-feeding
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.

Beconase Allergy / Hayfever should not be used during lactation without consulting a doctor.

4.7 Effect on Ability to Drive and Use Machines

Not relevant.

4.8 Undesirable Effects

Adverse reactions listed below are based on clinical trial data and classified according to MedDRA frequency and System Organ Class. Frequency categories are defined according to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Respiratory, thoracic and mediastinal disorders	Rare	nasal septal performation, dryness and irritation of throat and nose, epistaxis, unpleasant smell and taste
Eye disorders	Rare:	raised intra ocular pressure, glaucoma, cataract

	Not known:	Vision, blurred (see also section 4.4)
Immune system disorders	Very rare:	hypersensitivity reactions including rashes, urticaria, pruritus, erythema, oedema of the eyes, face, lips and throat, anaphylactoid / anphylactic reactions, dyspnea and/or bronchospasms.

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 the MHRA Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The only harmful effect that follows inhalation of large amounts of the drug over a short time period is suppression of hypothalamic-pituitary adrenal (HPA) function. No special emergency action need be taken. HPA function recovers in a day or two after discontinuation of treatment with Beconase Allergy / Hayfever.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Following topical administration, beclometasone 17,21-dipropionate (BDP) produces potent anti-inflammatory and vasoconstrictor effects.

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

Beclometasone 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 reappearing.

5.2 Pharmacokinetic Properties

Absorption

Following intranasal administration of BDP in healthy males, 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% (95% CI 28%, 70%). After intranasal administration, <1% of the dose is absorbed by the nasal mucosa. The remainder, after being cleared from the nose, either by drainage or mucocilary clearance, is available for absorption from the gastrointestinal tract. Plasma B-17-MP is almost entirely due to conversion of BDP absorbed from the swallowed dose.

Following oral administration of BDP the systemic absorption was also assessed by measuring the plasma concentrations of its active metabolite B-17-MP, for which the absolute bioavailability following oral administration is 41% (95% CI 27%, 62%).

Following an oral dose, B-17-MP is absorbed slowly with peak plasma levels reached 3-5 hours after dosing.

Distribution

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

Biotransformation
BDP is cleared very rapidly from the circulation and plasma concentrations are undetectable (< 50pg/ml) following oral or intranasal dosing. There is rapid metabolism of the majority of the swallowed portion of BDP during its first passage through the liver. 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 1201/h) with corresponding terminal elimination half-lives of 0.5h and 2.7h. Following oral administration of tritiated 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.

5.3 Preclinical safety data

None reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Avicel RC 591 (Microcrystalline Cellulose and Carboxymethylcellulose Sodium)	USNF
Anhydrous Dextrose for parenteral use	BP
Benzalkonium Chloride (added as Benzalkonium Chloride solution)	BP
Phenylethyl Alcohol	USP
Polysorbate 80	BP
Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months. After first opening the shelf life is 3 months.

6.4 Special Precautions for Storage

Beconase Allergy / Hayfever should not be stored above 25 C. Keep container in the outer carton**.** Do not refrigerate.

6.5 Nature and contents of container

Beconase Allergy / Hayfever is supplied in 17ml or 25ml amber glass bottles fitted with a metering, atomising pump and nasal applicator or in a 20ml or 30ml plastic bottle fitted with a tamper resistant, metering atomising pump and nasal applicator. A combined nasal adaptor/actuator covered with a dust cap is fitted on the pump. The glass bottle provides 80, 100, 180 or 200 metered sprays, and the plastic bottle provides 100, 180 or 200 sprays.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Omega Pharma Ltd.
Wrafton,
Braunton,
Devon,
EX33 2DL,
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 02855/0064

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 2007

10 DATE OF REVISION OF THE TEXT

21/11/2022