NEW ZEALAND DATA SHEET

1. PRODUCT NAME

BECONASE Allergy & Hayfever nasal spray suspension 50 mcg/dose.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BECONASE Allergy & Hayfever contains microfine beclometasone dipropionate. Each 100 mg spray delivered by the nasal applicator contains 50 micrograms beclometasone dipropionate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

BECONASE Allergy & Hayfever is a white aqueous suspension delivered by a metering, atomising pump.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BECONASE Allergy & Hayfever is indicated for the prophylaxis and treatment of seasonal and perennial allergic rhinitis including hayfever.

4.2 Dose and method of administration

BECONASE Allergy & Hayfever is for administration by the intranasal route only.

Adults and children over 12 years of age:
The recommended dose is 100 micrograms into each nostril twice daily. Total daily administration should not normally exceed 400 micrograms.

Once symptoms are controlled, protection can be maintained at half the dose; one spray into each nostril twice daily. This dose may need to be increased if symptoms worsen.

For full therapeutic benefit regular usage is essential. The co-operation of the patient should be sought to comply with the regular dosage schedule and it should be explained that maximum relief may not be obtained within the first few applications.

For children under twelve years old, there are insufficient clinical data to recommend use.

Do not use for more than six months without obtaining medical advice.

4.3 Contraindications

Hypersensitivity to any component of BECONASE Allergy & Hayfever.

4.4 Special warnings and precautions for use

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.

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

If recommended doses of intranasal beclometasone are exceeded or if individuals are particularly sensitive or predisposed by virtue of recent systemic steroid therapies, systemic effects may occur, including reduction in growth velocity.

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.

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 Interactions with other medicines and other forms of interaction

No known interactions have been observed.

4.6 Fertility, pregnancy and lactation

Use in pregnancy
Administration of medicines 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.

Use in lactation
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 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 medicine be weighed against the potential hazards to the mother and baby.

4.7 Effects on ability to drive and use machines

Beclometasone dipropionate is unlikely to produce an effect on the ability to drive or use machines.

4.8 Undesirable effects

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to https://nzphvc.otago.ac.nz/reporting/.

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

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

Occasionally headache has been reported.

Rare cases of raised intraocular pressure or glaucoma in association with intranasal formulations of beclometasone have been reported. Central serous chorioretinopathy (CSCR) has been reported for all corticosteroid containing products.

Hypersensitivity reactions including rashes, urticaria, pruritis, erythema and oedema of the eyes, face, lips and throat have been reported.

4.9 Overdose

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

The only harmful effect that follows inhalation of larger amounts of the medicine over a short time period is suppression of hypothalamic-pituitary-adrenal (HPA) function. No special emergency action need be taken.

Treatment with BECONASE Allergy & Hayfever should be continued at the recommended dose. HPA function recovers in a day or two.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Following topical administration beclometasone 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 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 re-appearing by reducing the sensitivity of nasal membranes.

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 concentrations of its active metabolite B-17-MP, for which the absolute bioavailability following oral administration is 41%.

Metabolism

BDP is cleared very rapidly from the circulation and plasma concentrations are undetectable (< 50pg/mL) following oral or intranasal dosing. Metabolism is mediated 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.

Distribution

The tissue distribution at steady-state for BDP is moderate (20L) but more extensive for B-17-MP (424L). Plasma protein binding is moderately high (87%).

Elimination

The elimination of BDP and B-17-MP are characterised by high plasma clearance (150 and 120L/hour) with corresponding terminal elimination half-lives of 0.5 hours and 2.7 hours. 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. 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 and phenylethylalcohol.

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C, but do not refrigerate. Protect from light. Discard 3 months after first using.

6.5 Nature and contents of container

BECONASE Allergy & Hayfever is supplied in an amber glass bottle fitted with a metering, atomising pump and nasal applicator. Each bottle contains 200 sprays.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. MEDICINE SCHEDULE

Pharmacy medicine.

8. SPONSOR

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland, New Zealand

Telephone: (09) 918 5100
Email: aspen@aspenpharma.co.nz

9. DATE OF FIRST APPROVAL

1 April 1997

10. DATE OF REVISION OF THE TEXT

14 June 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
6.4	Addition of storage information to align with labelling.
8	Addition of telephone and email.
all	Update to the SPC-style.
4.4 & 4.8	4.4: Addition of ‘visual disturbance’ safety text at the request of Medsafe. 4.8: Addition of central serous chorioretinopathy (CSCR) as an adverse event.