NEW ZEALAND DATA SHEET

1. BECLOCLEAR 100 (100 micrograms per spray, nasal spray solution)

BecloClear 100 (100 micrograms per spray, nasal spray solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Beclometasone dipropionate (anhydrous) 100 micrograms per spray

Excipient with known effect:
Benzalkonium chloride

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BecloClear 100 is indicated in adults and children over six years of age for the prevention and treatment of seasonal and perennial allergic rhinitis and vasomotor rhinitis. BecloClear 100 can significantly delay the recurrence of nasal polyps in those patients who have undergone nasal polypectomy. In those polyps that do recur, BecloClear 100 can suppress their increase in size.

4.2 Dose and method of administration

BecloClear 100 should be shaken before use.

Prior to first use, the nasal spray pump should be primed by spraying five discarded sprays into the air. Thereafter, BecloClear 100 should be re-primed with one discarded spraying following 7 or more days of no use, and after nozzle cleaning.

Dose
For adults and children over 6 years of age:
The recommended dosage is one spray into each nostril twice daily. Total daily administration should not normally exceed 400 micrograms.

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.

Paediatric population
The safety and efficacy of BecloClear 100 in children under six years have not been established.

Method of administration
BecloClear 100 is for administration by the intra-nasal route only.

4.3 Contraindications

Hypersensitivity to the active substance or 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 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 (see section 4.4, 'Paediatric population'), 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. Care must be taken while transferring patients from systemic steroid treatment to BecloClear 100 if there is any reason to suppose that their adrenal function is impaired.

Infections of the nasal passages and paranasal sinuses should be appropriately treated but do not constitute a specific contraindication to treatment with BecloClear 100.

Although BecloClear 100 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.

Paediatric population

Continuous long term treatment of children is not recommended.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure. BecloClear 100 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 intra-nasal 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.

Fertility

No data.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 and <1/10), uncommon (≥ 1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data. In assigning adverse reaction frequencies, the background rates in placebo groups were not taken into account, since these rates were generally comparable to those in the active treatment group.

System Organ Class	Adverse Event	Frequency
Immune system disorders	Hypersensitivity reactions including:	
	Rash, urticaria, pruritis, erythema.	Common
	Angioedema	Very rare
	Dyspnoea and/or bronchospasm	Very rare
	Anaphylactoid/anaphylacticreactions	Very rare
Nervous system disorders	Unpleasant taste, unpleasant smell.	Common
Eye disorders	Glaucoma, raised intraocular pressure, cataract.	Very rare
Respiratory, Thoracic & Mediastinal disorders	Epistaxis, nasal dryness, nasal irritation, throat dryness, throat irritation.	Common
	Nasal septum perforation.	Very rare

Systemic effects of nasal corticosteroids may occur particularly when used at high doses for prolonged periods (see section 4.4).

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: https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

The only harmful effect that follows inhalation of large 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 BecloClear 100 should be continued at the recommended dose. HPA function recovers in a day or two.

There is no specific treatment for an overdose of beclometasone dipropionate. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Following topical administration beclometasone 17, 21-dipropionate (BDP) produces potent anti-inflammatory and vaso-constrictor 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 mucociliary 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 in healthy males, 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%).

Metabolism

BDP is cleared very rapidly from the circulation and plasma concentrations are undetectable (< 50 pg/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.

Distribution

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

Elimination

The elimination of BDP and B-17-MP are characterised by high plasma clearance (150 and 120 L/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.

5.3 Preclinical safety data

No clinically relevant findings were observed in preclinical studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Phenylethyl alcohol
Polysorbate
Dispersible cellulose
Glucose (anhydrous)
Dilute hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Discard three months after first using the spray.

6.4 Special precautions for storage

Store below 30°C. Protect from light. Do not refrigerate.

For storage conditions after first opening of the medicine, see section 6.3.

6.5 Nature and contents of container

BecloClear 100 is supplied in 30 mL HDPE bottles fitted with a metering pump, a nasal applicator and a dust cover. Each bottle provides 200 sprays.

6.6 Special precautions for disposal

No special requirements.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

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