New Zealand Data Sheet

BECONASE® Allergy & Hayfever 12 Hour

Beclomethasone dipropionate USP (50 micrograms per actuation) Aqueous Nasal Spray

Presentation

BECONASE Allergy & Hayfever 12 Hour is a presentation of a white aqueous suspension of microfine beclomethasone dipropionate USP delivered by a metering, atomising pump. Each 100 mg spray delivered by the nasal applicator contains 50 micrograms beclomethasone dipropionate USP.

Indications

BECONASE Allergy & Hayfever 12 Hour is indicated for the prophylaxis and treatment of seasonal and perennial allergic rhinitis including hayfever.

Dosage and Administration

BECONASE Allergy & Hayfever 12 Hour 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.

Contraindications

Hypersensitivity to any component of BECONASE Allergy & Hayfever 12 Hour.

Warnings and Precautions

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 12 Hour.

Care must be taken while transferring patients from systemic steroid treatment to BECONASE Allergy & Hayfever 12 Hour if there is any reason to suppose that their adrenal function is impaired.

If recommended doses of intranasal beclomethasone 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 12 Hour 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.

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 beclomethasone 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 beclomethasone dipropionate into the milk of lactating animals have been performed. It is reasonable to assume that beclomethasone 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 beclomethasone 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.

Effects on ability to drive and use machines

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

Adverse Effects

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 beclomethasone have been reported.

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

Interactions

No known interactions have been observed.

Overdose

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 12 Hour should be continued at the recommended dose. HPA function recovers in a day or two.

Further Information

Pharmacodynamic Properties

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.

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, beclomethasone-21-monopropionate (B-21-MP) and beclomethasone (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.

Preclinical Safety Data

No data included.

List of excipients

Microcrystalline cellulose, carboxymethylcellulose sodium, glucose anhydrous, polysorbate 80, purified water, benzalkonium chloride and phenylethylalcohol.

Pharmaceutical Precautions

Incompatibilities

None reported.

Shelf Life

24 months

Special Precautions for Storage

Store below 30°C, but not in a refrigerator.

Package Quantities

BECONASE Allergy & Hayfever 12 Hour is supplied in an amber glass bottle fitted with a metering, atomising pump and nasal applicator. Each bottle contains 200 sprays.

Medicine Schedule

Pharmacy Medicine

Sponsor Details

Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

Date of Preparation

Date: 10 March 2015