

NEW ZEALAND DATA SHEET

ALANASE

Beclometasone dipropionate Aqueous Nasal Spray
50 µg & 100 µg per actuation



Presentation

ALANASE Aqueous Nasal Spray (50 micrograms per actuation) is an almost white opaque suspension of microfine Beclometasone dipropionate delivered by a metering, atomising pump. Each 100mg spray delivered by the nasal applicator contains 50 µg Beclometasone dipropionate.

ALANASE 100 Aqueous Nasal Spray (100 micrograms per actuation) is an almost white opaque suspension of microfine Beclometasone dipropionate delivered by a metering, atomising pump. Each 100mg spray delivered by the nasal applicator contains 100 µg Beclometasone dipropionate.

Uses

Actions

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 reappearing by reducing the sensitivity of nasal membranes.

Pharmacokinetics

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.

Preclinical safety data

No data included.

Indications

ALANASE Aqueous Nasal Spray (50 µg per actuation) is indicated for the short-term prevention and treatment of seasonal allergic rhinitis (hay fever).

ALANASE 100 Aqueous Nasal Spray (100 µg per actuation) is indicated for the prevention and treatment of seasonal and perennial allergic rhinitis and vasomotor rhinitis.

ALANASE and ALANASE 100 can significantly delay the recurrence of nasal polyps in those patients who have undergone nasal polypectomy. In those polyps that do recur, ALANASE and ALANASE 100 can suppress their increase in size.

Dosage and Administration

ALANASE and ALANASE 100 Aqueous Nasal Spray should be shaken before use.

ALANASE (50 micrograms per actuation):

For adults and children over 12 years of age:

Initially one or two sprays into each nostril twice a day (morning and night), then after 2 to 3 days, one spray into each nostril twice a day.

Do not use ALANASE (50 µg per actuation) for children under 12 years of age without first consulting with a doctor.

If hayfever symptoms do not improve within 7 days of treatment with ALANASE, consult with a doctor.

ALANASE 100 (100 µg per actuation):

For adults and children over 6 years of age:

The recommended dosage is one spray into each nostril twice daily.

For some patients, a dosage regimen of 50 micrograms into each nostril three or four times daily may be preferred. 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.

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

ALANASE and ALANASE 100 Aqueous Nasal Spray's are for administration by the intra-nasal route only.

Contraindications

Hypersensitivity to any components of ALANASE.

Warnings and Precautions

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

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 WARNINGS and PRECAUTIONS, Paediatric Use section), cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Care must be taken while transferring patients from systemic steroid treatment to ALANASE and ALANASE 100 if there is any reason to suppose that their adrenal function is impaired.

Although ALANASE and ALANASE 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 Use:

Controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in paediatric patients. This effect has been observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in paediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with intranasal corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with intranasal corticosteroids has not been adequately studied. The growth of paediatric patients receiving intranasal corticosteroids, should be monitored routinely (e.g. via stadiometry). The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of safe and effective noncorticosteroid treatment alternatives. To minimize the systemic effects of intranasal corticosteroids, each patient should be titrated to his/her lowest effective dose.

Continuous long term treatment of children is not recommended.

Concomitant Corticosteroid Therapy:

Should ALANASE be prescribed for patients already using corticosteroids, care should be taken to ensure that the combined daily intake via all routes of administration is considered when determining total daily corticosteroid dose.

Use during Pregnancy and Lactation:

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 intra-nasal application ensures minimal systemic exposure.

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 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.

Effects on Ability to Drive and Use Machines:

Beclometasone 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 reported rarely.

Occasionally headache has been reported.

Rare cases of raised intraocular pressure or glaucoma in association with intranasal formulations of beclometasone have been reported.

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

Systemic side effects may occur if the dose is exceeded over a prolonged period (see WARNINGS and PRECAUTIONS).

Cases of growth suppression have been reported for intranasal corticosteroids (see WARNINGS and PRECAUTIONS, Paediatric Use section).

Interactions

No known interactions have been observed.

Overdosage

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 ALANASE and ALANASE 100 Aqueous Nasal Spray should be continued at the recommended dose. HPA function recovers in a day or two.

Pharmaceutical Precautions

ALANASE and ALANASE 100 should be protected from the light and stored below 25°C. Do not refrigerate.

Discard three months after first using the spray.

Medicine Classification

ALANASE: Pharmacy Medicine.

ALANASE 100: Prescription Medicine.

Package Quantities

ALANASE and ALANASE 100 are supplied in amber glass bottles fitted with a metering, atomising pump and nasal applicator. Both dosage strengths provide 200 actuations.

Further Information

List of excipients: benzalkonium chloride, phenethyl alcohol, polysorbate, dispersible cellulose, glucose (anhydrous) and purified water.

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