[GSK logo]

BECONASE AQUEOUS NASAL SPRAY

Beclomethasone-dipropionate

QUALITATIVE AND QUANTITATIVE COMPOSITION

BECONASE Aqueous Nasal Spray is a presentation of an aqueous suspension of microfine beclomethasone dipropionate delivered by a metering, atomising pump. Each 100 mg spray delivered by the nasal applicator contains 50 micrograms beclomethasone.

PHARMACEUTICAL FORM

Aqueous Nasal Spray.

CLINICAL PARTICULARS

Indications

Prophylaxis and treatment of perennial and seasonal allergic rhinitis and vasomotor rhinitis. Beclomethasone dipropionate BP has a potent anti-inflammatory effect within the respiratory tract at doses which are not systemically active.

Dosage and Administration

BECONASE is for administration by the intranasal route only.

Adults and Children over 6 years of age:

The recommended dose is two applications into each nostril twice daily.

A dosage regimen of one application into each nostril three or four times daily may be preferred.

Total daily administration should not normally exceed 8 puffs (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.

Children under six years old:

There are insufficient clinical data to recommend use.

Contraindications

BECONASE Aqueous Nasal Spray is contraindicated in patients with a history of hypersensitivity to any of its components.

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 *BECONASE* Aqueous Nasal Spray.

Care must be taken while transferring patients from systemic steroid treatment to *BECONASE* Aqueous Nasal Spray if there is any reason to suppose that their adrenal function is impaired.

Systemic effects with nasal corticosteroids have been reported, 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.

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. Visual disturbances has been reported, including cataract, glaucoma or central serous chorioretinopathy.

Although *BECONASE* Aqueous Nasal Spray 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.

Interactions

None reported.

Pregnancy and Lactation

Administration of drugs 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 *BECONASE* 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.

The excretion of beclometasone dipropionate in milk has not been studied in animals. It is reasonable to assume that beclometasone dipropionate is secreted in milk but at the dosage used for the intranasal application, there is low potential for significant levels in breast milk. *BECONASE* should only be used in a nursing mother if the expected benefit justifies the risk to the infant.

Effects on Ability to Drive and Use Machines

None reported.

Adverse Reactions

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.

Immune system disorders

Very rare: Hypersensitivity reactions including rashes, urticaria, pruritis, erythema and angioedema, anaphylactoid/anaphylactic reactions, bronchospasm.

Nervous system disorders

Common: Unpleasant taste, unpleasant smell.

Eye disorders

Very rare: Glaucoma, raised intraocular pressure, cataract.

Respiratory, thoracic and mediastinal disorders

Common: Epistaxis, nasal dryness, nasal irritation, throat dryness, throat irritation.

Very rare: Nasal septal perforation.

Overdose

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

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.

The only harmful effect that follows inhalation of larger amounts of the drug over a short time period is suppression of hypothalamic-pituitary-adrenal (HPA) function. No special emergency action need be taken. Treatment with *BECONASE* Aqueous Nasal Spray should be continued at the recommended dose. HPA function recovers in a day or two.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

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.

BECONASE 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.

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 (< 50 pg/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/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. The renal clearance of BDP and its metabolites is negligible.

PHARMACEUTICAL PARTICULARS

List of Excipients

Microcrystalline cellulose.
Carboxymethylcellulose sodium.
Glucose anhydrous.
Polysorbate 80.
Purified water.
Benzalkonium chloride.
Phenylethylalcohol.
Hydrochloric acid.

Incompatibilities

None reported.

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

Store below 30°C.

Do not refrigerate.

Discard three months after using the spray.

Nature and Contents of Container

BECONASE Aqueous Nasal Spray is supplied in a polypropylene bottle fitted with a metering, atomizing pump and nasal applicator.

Each bottle provides approximately 200 metered sprays in recommended use.

How to use Beconase Aqueous Nasal Spray

Fig. 1 Before using, gently blow your nose to clear your nostrils and remember that, unless otherwise directed by your doctor, the usual dosage is two sprays in each nostril twice daily.

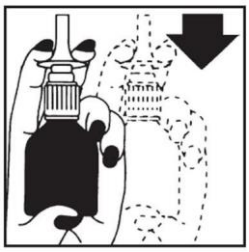

Fig. 2 To prepare for use, first shake the bottle, then remove the clear dust cap and hold as shown. If you are using for the first time or have not used the spray for a week or more, test by spraying into the air until the jet appears as a fine mist.
Do this by pressing downwards on the white collar with the forefinger and middle finger using your thumb to support the base of the bottle.

Fig. 3 To use, close one nostril by placing your thumb over the opening. Insert the nosepiece into the other nostril.
Then, whilst gently breathing in, press downwards on the white collar with the forefinger and middle finger using your thumb to support the base of the bottle.

Fig. 4 Breathe out through your mouth and repeat for your second spray in the same nostril.

Fig. 5 Now, repeat the whole process in the other nostril.

Fig. 6 On completion replace clear dust cap.

Cleaning
To clean the nasal applicator, remove the clear dust cap, press gently upwards on the white collar and the nasal applicator will come free.
Wash the applicator and dust cap under a cold tap. Dry and replace with the clear dust cap back in position.
If the nasal applicator becomes blocked, remove the clear dust cap, unscrew the complete pump mechanism and soak it in warm water for a few minutes. Rinse under a cold tap, dry and refit to bottle.

Caution
Beconase Aqueous Nasal Spray is not intended to give rapid relief of your nasal symptoms. It has been developed to control the underlying disorders responsible for your attacks so it is important that you should use it regularly at the times recommended by your doctor.

Storage
Protect from light. Store below 30°C but do not refrigerate. Discard three months after first using the spray.

Manufactured by:
Glaxo Wellcome S.A., Aranda de Duero, Spain.

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