

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nasobec Allergy 50 Micrograms Aqueous Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mg spray contains 50 micrograms beclometasone dipropionate.

Excipient: each spray contains 0.02mg benzalkonium chloride

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

A white opaque suspension, free from any visible matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Nasobec Allergy prevents and relieves nasal congestion, sneezing and a runny, itchy nose due to hayfever and other seasonal allergic conditions. Once nasal congestion is cleared the pressure and pain around the eyes is also reduced. Beclometasone Dipropionate has anti-inflammatory glucocorticoid properties.

4.2 Posology and method of administration

Regular usage is essential for full therapeutic benefit. Nasobec Allergy quickly starts to bring relief and reduce swelling in the nose although it may take a few days to build up to its maximum effect.

Adults 18 years of age and over:-

Two sprays twice daily into each nostril (400mcg/day) is the recommended initial dosage. It may be preferable for some patients to administer a single spray into each nostril three or four times daily.

Once control of symptoms has been achieved move the dosage down to one spray twice daily into each nostril (200 micrograms beclometasone dipropionate per day).

The minimum dose should be used at which effective control of symptoms is maintained.

The total dosage for any 24 hour period should not normally exceed eight sprays, i.e. 400 micrograms of beclometasone dipropionate.

If there is no response after 14 days of treatment, medical advice should be sought.

Nasobec Allergy is for nasal use only.

Do not use continuously for longer than 3 months without consulting your doctor.

Elderly: Dosage as for adults.

Individuals under the age of eighteen years: Nasobec Allergy is not indicated for children under the age of eighteen years, due to insufficient clinical data.

4.3 Contraindications

Patients with a history of hypersensitivity to any of the excipients.

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

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 corticosteroids, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should also 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 corticosteroids cover should be considered during periods of stress or elective surgery.

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

Although Nasobec Allergy will control seasonal allergic rhinitis in the majority of cases, concomitant therapy to control eye symptoms may be necessary during a heavy challenge to allergens.

Infections of the nasal passages and paranasal sinuses should be appropriately treated but Nasobec Allergy therapy need not be stopped.

The product contains benzalkonium chloride which is an irritant and may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Early studies in animals have demonstrated an increase in foetal cleft palate and growth retardation following maternal ingestion of high corticosteroid doses. However, direct intranasal application at the recommended doses ensures minimal systemic exposure.

The use of beclometasone dipropionate in pregnancy requires that the possible benefits of the drug be weighed against the possible hazards. The drug has been in widespread use for many years without apparent ill consequence.

Use during lactation

It is probable that beclometasone is excreted in milk. However, given the relative low doses used by the nasal route, the levels are likely to be low. In mothers breast feeding their baby the therapeutic benefits of the drug should be weighed against the potential hazards to mother and baby.

4.7 Effects on ability to drive and use machines

Nasobec Allergy has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. In very rare cases, a nasal septal perforation can develop during therapy.

Dryness and irritation of the nose and throat as well as blood stained crusts in the nose can occur when taking nasal sprays but these conditions are not progressive and are seldom troublesome. An unpleasant smell and taste are rarely reported.

Rare cases of raised intra-ocular pressure or glaucoma in association with intranasal formulations of beclometasone dipropionate have been reported.

Widespread use of beclometasone dipropionate for a decade has shown no serious local damage to mucous membranes.

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

4.9 Overdose

Suppression of the HPA function is the only harmful effect that would arise from taking large amounts of beclometasone dipropionate over a short period of time. No emergency procedure need be undertaken and treatment with Nasobec Allergy should continue at the recommended dose. The HPA function reverts back to normal within a day or two.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nasal preparations for topical use, corticosteroids: R01AD01

Beclometasone dipropionate is the diester of beclometasone, a synthetic glucocorticoid which demonstrates potent anti-inflammatory and immunosuppressant properties within the nasal tract without significant activity at recommended doses. This drug is stated to exert a topical effect on the lungs without significant systemic activity at recommended dose, although the mechanisms of action are as yet unknown.

5.2 Pharmacokinetic properties

The pharmacokinetics of beclometasone dipropionate have not been extensively studied. The currently available chemical methods are not of sufficient sensitivity to measure therapeutically relevant plasma concentrations, particularly those occurring following inhalation.

a) General characteristics of the active substance

Absorption

Beclometasone dipropionate is readily absorbed from the gastro-intestinal tract. It is also well absorbed from sites of local application. When administered by topical application, as in the case of Aqueous Nasal Spray, sufficient beclometasone dipropionate may be absorbed to give systemic effects.

Distribution

The drug is rapidly distributed to all body tissues. It crosses the placenta and may be excreted in small amounts in breast milk.

Elimination

After metabolism in the liver and kidney, the drug is excreted in the urine.

b) Characteristics in patients

As above

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Phenylethyl alcohol
Polysorbate 80
Glucose anhydrous
Dispersible cellulose
Hydrochloric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years unopened.
Discard three months after first using the spray.

6.4 Special precautions for storage

Do not store above 25°C.
Keep in the original container.
Do not refrigerate or freeze.

6.5 Nature and contents of container

Nasobec is supplied in polyethylene bottles of 15ml capacity containing a nominal 100 doses. Each bottle is fitted with a metering pump with a built in nasal adaptor designed to deliver a nominal 100 milligrams of suspension per spray.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Directions for use are detailed in the patient information leaflet.

7 MARKETING AUTHORISATION HOLDER

Norton Waterford
T/A IVAX Pharmaceuticals Ireland
Unit 301
IDA Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 436/28/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2006

Date of last renewal: 31st March 2011

10 DATE OF REVISION OF THE TEXT

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