

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nasobec 50 Micrograms Aqueous Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mg spray contains 50 micrograms beclometasone dipropionate.

Excipients: contains benzalkonium chloride solution 0.02 microlitres.

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

For the prophylaxis and treatment of perennial and seasonal allergic rhinitis including hay fever and vasomotor rhinitis.

Nasobec is indicated in adults and children aged six years and over.

Nasobec can significantly delay the recurrence of nasal polyps after nasal polypectomy. Where polyps do recur, Nasobec can suppress their increase in size.

4.2 Posology and method of administration

Posology

Adults and children over six years old: Two sprays twice daily into each nostril (400 mcg/day) is the recommended dosage. It may be preferable for some patients to administer a single spray into each nostril three or four times daily. Once control has been established it may be possible to maintain control with fewer sprays. Dosage should be adjusted in each individual case to the lowest dose that achieves effective control of the symptoms.

The maximum daily dose of 400 mcg (eight sprays) should not normally be exceeded.

It should be made clear to patients that full therapeutic benefit will only be achieved after a few days treatment.

Elderly: Dosage as for adults.

Paediatric population:

The safety and efficacy of Nasobec in children aged less than six years old has not been established.

Method of administration

For administration by the intranasal route only.

4.3 Contraindications

Hypersensitivity to beclomethasone dipropionate 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, cataract, glaucoma, blurred vision, 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.

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

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, additional systemic corticosteroids cover should be considered during periods of stress or elective surgery.

Infections of the nasal passages and paranasal sinuses should be appropriately treated before treatment with Nasobec.

The use of the preparation should be avoided in the presence of untreated infections.

Particular care should be taken to minimise use of topical corticosteroids in patients with immunosuppression.

Particular caution is required in patients with a history of, or existent tuberculosis.

Cataracts have been associated with systemic steroid therapy. There have been rare reports of cataracts developing in patients who have been using intranasal or inhaled corticosteroids for prolonged periods, although together causes, including exposure to systemic steroids, cannot be excluded.

Although Nasobec 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.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

Beclometasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. Intra-uterine growth retardation cannot be ruled out during long-term therapy. 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.

Breastfeeding

It is probable that beclometasone is excreted in milk. 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 has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Nasally administered glucocorticoids can cause undesirable systemic effects, especially if high doses are administered for extended periods.

The frequencies of adverse events are ranked according to the following: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

System Organ Class	Undesirable Effect	Frequency
Immune system disorders	Hypersensitivity reactions including: rash, urticaria, pruritus, erythema and oedema of the face, eyes, lips and throat, bronchospasm, anaphylactic/anaphylactoid reactions	Very rare
Nervous system disorders	Smell or taste alteration	Rare
Eye disorders	Blurred vision (see also section 4.4)	Rare
	Increased intra-ocular pressure including glaucoma, central serous retinopathy	Not known
Respiratory, thoracic and mediastinal disorders	Nasal dryness, nasal irritation and throat irritation, nosebleeds (epistaxis)	Rare
	Nasal septum perforation	Not known

Paediatric population

Growth retardation has been reported in children receiving nasal corticosteroids (see section *Special warnings and precautions for use*).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Exceeding the maximum prescribed dose for a short time can cause suppression of the HPA function.

No special emergency measures are necessary. Treatment should be continued at the prescribed dosage and the function of the hormonal feedback mechanism will generally be restored after 1-2 days.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: decongestants and other nasal preparations for topical use, corticosteroids, ATC code: R01AD01

Following topical administration beclomethasone 17, 21-dipropionate (BDP) produces potent anti-inflammatory and vasoconstrictor 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.

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.

5.2 Pharmacokinetic properties

Synthetic glucocorticoid which demonstrates potent properties within the nasal tract without significant systemic activity at recommended doses.

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.

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.

Characteristics in patients

As above.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Phenylethyl alcohol
Polysorbate 80
Glucose
Microcrystalline Cellulose and Carmellose Sodium
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

Store below 25°C.

Keep the bottle in the outer carton.

6.5 Nature and contents of container

Nasobec is supplied in polyethylene bottles of 30 ml capacity containing a nominal 200 doses fitted with a metering pump with a built in nasal adaptor. Each bottle is 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

Use within three months of starting treatment.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/055/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 March 1999

Date of last renewal: 04 March 2009

10 DATE OF REVISION OF THE TEXT

January 2022