

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Nasivara 50 micrograms Aqueous Nasal Spray

Beclometasone Dipropionate Aqueous Nasal Spray

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each metered dose contains 50 micrograms of beclometasone dipropionate.

Excipient with known effect

Benzalkonium Chloride Solution – 0.01µL per spray

For the full list of excipients, see section 6.1.

## **3 PHARMACEUTICAL FORM**

Nasal spray, suspension.

Aqueous suspension for intranasal inhalation via metered dose atomising pump.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Beclometasone Dipropionate Aqueous Nasal Spray is indicated for the prevention and treatment of perennial and seasonal rhinitis, including hay fever and vasomotor rhinitis.

### **4.2 Posology and method of administration**

### Posology

It is important to use this product regularly in order to achieve maximum relief from the symptoms. It should be explained to the patient that full therapeutic benefit may not be experienced until after the first few doses of Beclometasone Dipropionate Aqueous Nasal Spray.

*Adults and Children (aged 6 years or over):* The recommended dosage is two sprays into each nostril twice a day (400 micrograms a day). Once control has been established, it may be possible to maintain control with fewer sprays. A dosage regimen of one spray into each nostril morning and evening has been shown to be efficacious in some patients. However, should symptoms recur, patients should revert to the recommended dosage of two sprays into each nostril morning and evening. The minimum dose should be used at which effective control of symptoms is maintained. A total of eight sprays (400 micrograms) daily should generally not be exceeded.

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 6 years old:* Not recommended

### Method of administration

For nasal administration only.

## **4.3 Contraindications**

Hypersensitivity to the active substance or to 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 and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses. 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 corticosteroid, if possible to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should 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 of higher than recommended doses being used then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

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

Infections of the nasal passages and paranasal sinuses should be appropriately treated but do not constitute a specific contraindication to treatment with Beclometasone Dipropionate Aqueous Nasal Spray.

Although Beclometasone Dipropionate Aqueous Nasal Spray will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate additional therapy particularly to control eye symptoms.

Use should also be avoided after nasal surgery (until healing has occurred) and in pulmonary tuberculosis.

#### 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.

#### Beclometasone Dipropionate Aqueous Nasal Spray contains Benzalkonium Chloride

This medicine contains 0.010 µL benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Long-term use may cause oedema of the nasal mucosa.

### **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. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure.

Beclometasone Dipropionate Aqueous Nasal Spray delivers beclometasone dipropionate directly to the nasal mucosa and so minimises systemic exposure.

The use of beclometasone dipropionate should be avoided during pregnancy unless thought essential by the doctor.

### *Breast-feeding*

No specific studies examining the transference of beclomethasone 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 intranasal administration 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 drug be weighed against the potential hazards to the mother and baby.

## 4.7 Effects on ability to drive and use machines

There are no reports of reactions to Beclometasone Dipropionate Aqueous Nasal Spray that would affect a patient's ability to drive or use machines.

## 4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $<1/10$ ), uncommon ( $\geq 1/1000$  and  $<1/100$ ), rare ( $\geq 1/10,000$  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.

System Organ Class	Adverse Event	Frequency
Immune system disorders	Hypersensitivity reactions including:	
	Rash, urticaria, pruritus, erythema.	Common
	Angioedema	Very rare
	Dyspnoea and/or bronchospasm	Very rare

	Anaphylactoid/anaphylactic reactions	Very rare
Nervous system disorders	Unpleasant taste, unpleasant smell.	Common
Eye disorders	Glaucoma, raised intraocular pressure, cataract.	Very rare
	Vision blurred (see section 4.4)	Not known
Respiratory, Thoracic & Mediastinal disorders	Epistaxis, nasal dryness, nasal irritation, throat dryness, throat irritation.	Common
	Nasal septum perforation.	Very rare

Systemic effects of nasal corticosteroids may occur particularly when used at high doses for prolonged periods.

Retardation in growth is possible, following extensive use in children (please refer to section 4.4 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **4.9 Overdose**

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

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.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use  
ATC code: R01AD01

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

BDP is a pro-drug with weak corticosteroid receptor binding affinity. It is hydrolysed via esterase enzymes to the highly 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.

## 5.2 Pharmacokinetic properties

### *Absorption*

The systemic absorption of BDP in healthy males following intranasal administration was assessed by measuring plasma concentrations of its active metabolite Beclometasone-17-monopropionate (B-17-MP), for which the absolute bioavailability following intranasal administration is 44% (95% CI 28%, 70%). After intranasal administration, <1% of the dose is absorbed by the nasal mucosa. The remainder, after being cleared from the nose either by drainage or mucociliary clearance, is available for absorption from the gastrointestinal tract. Plasma B-17-MP is almost entirely due to conversion of BDP absorbed from the swallowed dose.

Following oral administration of BDP in healthy males, the systemic absorption was also assessed by measuring the plasma concentrations of its active metabolites B-17-MP for which the absolute bioavailability following administration is 41% (95% CI 27%, 62%).

Following an oral dose, B-17-MP is absorbed slowly with peak plasma levels reached 3-5 hours after dosing.

### *Metabolism*

BDP is cleared very rapidly from the circulation and plasma concentrations are undetectable (<50 pg/ml) following oral or intranasal dosing. The majority of the swallowed portion of BDP is rapidly metabolised during its first passage through the liver. The main product of metabolism is the active metabolite (B-17-MP). Minor inactive metabolites, beclometasone-21-monopropionate (B-21-MP) and beclometasone are also formed but these contribute little to systemic exposure.

### *Distribution*

The tissue distribution at steady-state for BDP is moderate (201) but more extensive for B-17-MP (4241). Plasma protein binding of BDP is moderately high (87%).

### *Elimination*

The elimination of BDP and B-17-MP are characterised by high plasma clearance (150 and 120 l/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.

### **5.3 Preclinical safety data**

No clinically relevant findings were observed in preclinical studies.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Anhydrous glucose, microcrystalline cellulose and sodium carboxymethylcellulose (Avicel RC-591), polysorbate 80, phenylethyl alcohol, benzalkonium chloride solution and purified water.

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf life**

Unopened: 2 years.

After first opening the container: 3 months

### **6.4 Special precautions for storage**

Do not store above 30°C. Keep container in the outer carton. Do not refrigerate.

### **6.5 Nature and contents of container**

Beclometasone Dipropionate Aqueous Nasal Spray is supplied in either amber glass bottles or HDPE vials fitted with a metering, atomising pump and nasal applicator. Each bottle provides approximately 200 metered sprays.

## 6.6 Special precautions for disposal

Children should only use Beclometasone Dipropionate Aqueous Nasal Spray under the supervision of an adult. Always shake the container before use.

Instructions as shown in the leaflet:

1. Remove the cap from the nozzle. Make sure the nozzle is clean and clear of fluff and dirt. If you have not used your spray for a few days or if your spray is new, you will have to prime it before you can use it.

2. Priming your spray

Hold the bottle upright, with your thumb on the base and your forefinger and index finger either side of the collar. Now press the collar down with your fingers, making sure that the nozzle is pointing away from you. This will pump the spray, until a fine mist is produced. In case the mist does not appear, you may need to clean the nozzle.

Shake the spray vigorously up and down. Holding the spray well away from your nostril breathe out with your nose. Place the nozzle in one nostril, holding the bottle upright, and close your other nostril by pressing on the other side of your nose. Leaning your head slightly forward breathe in slowly and deeply through your nose. At the same time press down firmly on the collar with your fingers to squirt a spray and release the drug. Remove the nozzle from your nostril and slowly breathe out through your mouth. Repeat the procedure for the other nostril. Wipe the nozzle with a clean cloth and replace the cap after use.

3. Cleaning the nozzle

It is very important to keep the plastic cap and the nozzle clean, to prevent any build up of powder. Washing the applicator regularly (weekly) is recommended.

To clean, remove the plastic cap and pull the white collar upwards to remove the nozzle. Soak the nozzle and cap in warm water, then rinse. Dry thoroughly, then replace the nozzle and cap. Do not put the bottle into water. You may need to prime your spray before use.

## 7 MARKETING AUTHORISATION HOLDER

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