Beclomet Nasal Aqua 50mcg/dose nasal spray

Each millilitre contains:		
Beclomethason. dipropion.		0.555 mg
Benzalkon. chlorid.		0.1 mg
Glucos. anhydr.		
Polysorb. 80		
Avicel RC 591	q.s.	
Aq. purif.	ad	1 ml

Beclomet Nasal Aqua 50 mcg/dose nasal spray is a white or almost white aqueous suspension of beclomethasone dipropionate for nasal use. It forms a fine mist when sprayed. Beclomethasone dipropionate is a synthetic steroid derivative. It has a potent anti-inflammatory and antioedemic effect on the mucous membrane when administered into the nose. Beclomethasone acts topically and the absorption from the nasal mucous membrane is slight. Thus it acts in the superficial layers of the tissue, and with the recommended dosage, it is devoid of systemic effects.
Beclomethasone dipropionate is absorbed from the nasal mucosa. Part of the nasally administered dose of beclomethasone can pass the nose with inhaled air and retains in pharynx where it may be swallowed. This fraction undergoes a rapid first-pass in the liver to inactive metabolites. The drug that is absorbed from the nasal mucosa avoids this metabolism, but is ultimately metabolized in the liver. Beclomethasone dipropionate is metabolized to beclomethasone monopropionate and free beclomethasone and metabolites are mainly excreted in the faeces.
Beclomet Nasal Aqua 50 mcg/dose nasal spray is an aqueous suspension. It is an alternative to nasal aerosols, especially for patients suffering from dryness of nose caused by nasal aerosols.

Indications
Seasonal and perennial allergic rhinitis. Vasomotor rhinitis. Prevention of recurrence of nasal polyps after surgical removal.

Dosage and Administration
The preparation is intended for nasal use only. For optimum results, Beclomet Nasal Aqua spray should be used regularly. The therapeutic effects occurs after a few days' treatment. Treatment should not be continued beyond 3 weeks in the absence of significant symptomatic improvement. When the desired clinical effect is obtained, the maintenance dose should be reduced to the smallest amount necessary to control the symptoms.

Adults:
Recommended dosage is one to two sprays into each nostril once daily or one spray into each nostril four times daily. The total daily administration should not normally exceed 20 sprays (1mg).

Children:
One spray into each nostril two to four times daily according to clinical response. In children under 12 years old, the total daily administration should not normally exceed 10 sprays (0.5 mg).
For children under 6 years old, there are insufficient clinical data to recommend use.

Contraindications
The use of Beclomet Nasal Aqua is contraindicated in patients with a history of hypersensitivity to any of its components.

Side Effects/Adverse Reactions
The most common side effects are dryness and irritation of nose and throat and sneezing. Unpleasant taste and smell can occur. In some cases nasal secretion containing blood has been observed. Nasopharyngeal candidiasis is possible. Epistaxis has been reported rarely. Cases of growth suppression have been reported for intranasal corticosteroids (see PRECAUTIONS, Pediatric Use section).

Precautions/Warnings
Patients suffering from tuberculosis should be treated with care. Sinusitis must be treated properly. Patients should be thought the proper use of Beclomet Nasal Aqua to ensure the good clinical efficacy. They should also be aware that Beclomet Nasal Aqua has to be used regularly for optimal benefit. Patients should be advised that the drug will not provide immediate symptomatic relief and use of topical nasal decongestant or oral antihistamines may be necessary until the effects of intranasal beclomethasone dipropionate are fully manifested. Infections of the nasal passages and paranasal sinuses should be appropriately treated but do not constitute a specific contra-indication to treatment with Beclomet Nasal Aqua.
Care must be taken while transferring patients from systemic steroid treatment to Beclomet Nasal Aqua if there is any reason to suppose that their adrenal function is impaired.
A heavy challenge of summer allergens may in certain instances necessitate appropriate additional therapy particularly to control eye symptoms. In the continuous long-term treatment with intranasal steroids, the nasal mucosa should be inspected regularly, at least once a year. Intranasal corticosteroid should be used with caution until healing occurs in patients with recent nasal septal ulcers, nasal surgery or nasal trauma, since the drug may inhibit wound healing.

Use in Pregnancy and Lactation:
Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development, including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human fetus. It should be noted, however, that the fetal changes in animals occur after relatively high systemic exposure; direct intranasal application ensures minimal systemic exposure.
The use of beclomethasone dipropionate during pregnancy requires that the possible benefits of the drug be weighed against the possible hazards. It should be noted that the drug has been in widespread use for many years without apparent ill consequence.
The use of beclomethasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazard to the mother and baby.

Pediatric Use:
Controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in pediatric 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 or systemic corticosteroid exposure in pediatric 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 pediatric 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 minimise the systemic effects of intranasal corticosteroids, each patient should be titrated to his/her lowest effective dose.

Interactions with other medications
There are no known interactions with other drugs. However, if used synergistically with systemic or orally inhaled corticosteroids, the suppressive effect on adrenal function may be potentiated.

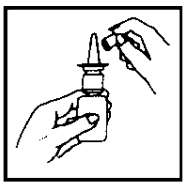
Overdosage
When used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may occur. If such changes occur, Beclomet Nasal Aqua should be discontinued slowly, consistent with acceptable procedures of discontinuing oral steroid therapy. The acute toxicity of beclomethasone dipropionate is low.

Packing
Bottle of 23 ml (= 200 doses)
Store below 30°C.
Keep out of reach of children.
Shelf-life: 3 years

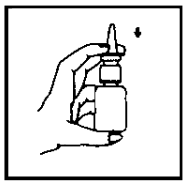
Manufactured by:
Orion Corporation, Kuopio Plant
Volttikatu 8, 70700 Kuopio, Finland
Date of Revision: 5 October 2017

Beclomet Nasal Aqua 50 mcg/dose nasal spray

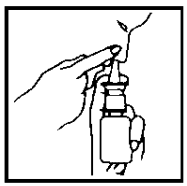
Instructions
Before using this nasal spray read these instructions and follow them carefully.



Picture 1
Blow your nose. Shake nasal spray container well and remove the protective cap at the top of the bottle.



Picture 2
Hold the nasal spray container as shown in the picture: keep your thumb at the bottom and forefinger and middle finger over the white collar. Press the collar down towards your thumb when spraying.



Picture 3
Place the nose piece in one nostril as shown in the picture. Close the other nostril by pressing with a finger. Breathe in while spraying, then breathe out slowly through your nose.

Picture 4
Cleaning: Remove the protective cap and gently detach the white collar from the container. Rinse the nose piece and the cap thoroughly in warm water. Dry and replace.

IMPORTANT!
For full therapeutic effect regular use is essential. Maximum relief is obtained within a few days. Do not exceed the dosage prescribed by physician.

ORION PHARMA

Jaakkoo-Taara Oy
Ruissalontie 4
FI-20200 Turku, Finland
Tel. +358 20 791 7600
E-mail: repro.jt@jt.fi
www.jt.fi

Colours are referential.
Please add changes as clearly as possible.

NOTE! We will charge changes that are against manuscript.
JT is not responsible of mistakes in approved proof.

JT Job No.: 339163
Item No.: 111974-5
Drawn Up: Taija Oksanen
Date: 2018-04-30/12:46:43
Client: ORION OYJ
Pharmacode: Pharmakoodi 586
Dimensions (mm): 150 x 210
Folded (W x L mm):
Drawing:
Material: -

Font size: 8...9

Colors: Black
Diecut

Fonts: MyriadPro-Bold
MyriadPro-Regular

Saila Kaipainen

Digitally signed by Saila Kaipainen
DN: cn=Saila Kaipainen, o=Packaging Technology, ou=Orion Corporation, email=saila.kaipainen@orion.fi, c=FI
Reason: Approved for printing
Date: 2018.05.02 11:10:17 +03'00'
Adobe Acrobat DC version: 2015.006.30119

Approved for printing / Date