

**PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Beclometasone Hayfever Relief Nasal Spray

(by OLS Numark)

(beclometasone dipropionate)

#### **Read all of this leaflet carefully because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

#### **In this leaflet:**

1. What Beclometasone is and what it is used for
2. Before you use Beclometasone
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## **1. WHAT BECLOMETASONE IS AND WHAT IT IS USED FOR**

Beclometasone belongs to a group of medicines called corticosteroids (commonly called steroids). Corticosteroids are used to reduce inflammation.

Beclometasone is used to relieve the symptoms of allergies (e.g. hayfever) such as sneezing, itchy nose and eyes or a blocked or runny nose by reducing the inflammation in the lining of your nose (rhinitis). Hayfever usually occurs in early summer and is caused by an allergy to pollen from plants and trees.

This medicine should not be confused with anabolic steroid tablets or injections, which may be misused by some athletes.

## **2. BEFORE YOU USE BECLOMETASONE**

#### **Do not use Beclometasone if:**

- you are allergic (hypersensitive) to beclometasone or any of the other ingredients of this medicine (see Section 6 for a list of other ingredients)
- you are under 18 years old.

#### **Take special care with Beclometasone:**

You should tell your doctor before taking this medicine:

- if you are suffering from either a nose infection or sinus trouble
- if you have recently had nasal surgery, if you have recently injured your nose or if you have ulcers in your nose
- if you are taking steroid tablets
- if you were previously being treated with a steroid injection or have taken steroid tablets for a long time, as you may notice a worsening of your symptoms.

It may take a few days before you notice an improvement in your symptoms. It is therefore important to use your nasal spray regularly.

Contact your doctor if you experience blurred vision or other visual disturbances.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

Some medicines may increase the effects of Beclometasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

### **Pregnancy and breast-feeding**

If you are pregnant, might become pregnant or are breast-feeding, speak to your doctor before taking Beclometasone. Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Beclometasone will not affect your ability to drive and use machines.

## **3. HOW TO USE BECLOMETASONE**

### **Dosage for Adults (including the elderly)**

You will need to use the Beclometasone spray regularly.

- Squirt two sprays into each nostril twice a day, every morning and evening.
- Once you start to feel better, a single spray into each nostril twice a day may be enough to control your hay fever.

**Do not** use more often than 8 sprays in 24 hours. If you feel no better after 10 days consult your doctor. You **should not** use Beclometasone continuously for longer than 3 months without consulting a doctor.

### **Normal Use**

1. Remove the dust-cap and lock-ring (if fitted). Shake the bottle gently (figure 1).
2. On first using the nasal spray, prepare for use by pressing down on the white collar using both your index and middle fingers. Keep the base supported with your thumb (figure 2). Continue to press down until the collar stops and then allow to return to its original position. Repeat this action until a fine spray appears. The first five attempts to produce a spray should be allowed to go to waste. Now the spray is ready to use.
3. To use the spray, first blow your nose gently. Closing one nostril off as shown, bend your head forward slightly. Hold the bottle upright and carefully insert the applicator into your other nostril (figure 3).
4. Slowly begin to breathe in through your nose and whilst doing so press down firmly on the white collar to produce a fine spray inside your nose. Breathe out through your mouth (figure 4).
5. Repeat steps 3 and 4 to squirt a second spray in the same nostril.

### **Cleaning**

Wash the nozzle frequently with warm water. This will prevent it from getting blocked. If the pump has not been used for a short period of time, re-priming may be necessary (see Step 2 above).

## **Children**

Children under 18 years of age should not use Beclometasone.

### **If you use more Beclometasone than you should**

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse. If you accidentally take too much of your medicine tell your doctor.

### **If you forget to use Beclometasone**

Take the next dose when it is due. **Do not** take a double dose to make up for a forgotten dose.

### **If you stop using Beclometasone**

Speak to your doctor first before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Beclometasone can cause side effects, although not everybody gets them.

If any of the following happen, **stop taking** Beclometasone and tell your doctor immediately:

**Rare** (may affect up to 1 in 1,000 people)

- cataract, raised pressure in the eye and glaucoma (an eye condition which can damage your sight causing blurred or loss of vision).
- sores on the lining of the nose and a small hole in the partition between the two nostrils may occur.

**Very rare** (may affect up to 1 in 10,000 people)

- severe allergic reaction such as swelling of the face, lips and/or throat, causing difficulty breathing or swallowing.

### Other possible side effects

**Common** (may affect up to 1 in 10 people)

- rash, including hives, itching or red skin

**Rare** (may affect up to 1 in 1,000 people)

- dryness and irritation of the nose and throat
- an unpleasant taste and smell, which can occur immediately after use.
- a small nose bleed, which will usually stop quickly.

**Very rare** (may affect up to 1 in 10,000 people)

- shortness of breath, wheezing

**Not known** (frequency cannot be estimated from the available data)

Some people may suffer side effects from small amounts of the steroid being absorbed into the body. This is more likely if you are on a high dose or use the spray for a long time. Possible side effects are:

- facial puffiness, increased body fat and thinning of the skin weight gain, rounded (moon-shaped) face and high blood pressure (Cushing's syndrome or Cushingoid features)
- a slowing of the rate of growth in children and adolescents.

It is important to follow the instructions given in this leaflet.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE BECLOMETASONE**

Keep out of the reach and sight of children.

Do not use Beclometasone after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Protect from light and do not refrigerate.

Once opened, you should not keep your medicine for longer than **3 months**. After three months, you should replace it even if it has not all been used up.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Beclometasone contains**

The active substance is beclometasone dipropionate. Each individual spray will contain 50 microgrammes of beclometasone dipropionate.

The other ingredients are anhydrous dextrose, polysorbate 80, dispersible cellulose, benzalkonium chloride 95%, phenylethanol and purified water.

### **What Beclometasone looks like and contents of the pack**

Each nasal spray consists of a small brown glass bottle with a plastic nasal applicator. It contains enough Beclometasone for 200 sprays.

### **Marketing Authorisation Holder**

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