



Beclometasone Dipropionate Aqueous Nasal Spray

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Beclometasone Dipropionate Aqueous Nasal Spray is and what it is used for
2. What you need to know before you use Beclometasone Dipropionate Aqueous Nasal Spray
3. How to use Beclometasone Dipropionate Aqueous Nasal Spray
4. Possible side effects
5. How to store Beclometasone Dipropionate Aqueous Nasal Spray
6. Contents of the pack and other information

1. WHAT BECLOMETASONE DIPROPIONATE AQUEOUS NASAL SPRAY IS AND WHAT IT IS USED FOR

Beclometasone Dipropionate Aqueous Nasal Spray contains a medicine called beclometasone dipropionate. This belongs to a group of medicines called steroids (also called 'cortico-steroids').

Steroids work by reducing inflammation. They reduce swelling and irritation in your nose which helps to relieve itching, sneezing and your blocked or runny nose.

Beclometasone Dipropionate Aqueous Nasal Spray is used to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hayfever.
- Inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BECLOMETASONE DIPROPIONATE AQUEOUS NASAL SPRAY

Do not take Beclometasone Dipropionate Aqueous Nasal Spray:

- If you are allergic to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Beclometasone Dipropionate Aqueous Nasal Spray:

- If you are already taking another steroid medicine
- If you have a cold or an infection in your nose
- If you have had nasal surgery
- If you have pulmonary tuberculosis.

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

If this medicine has been prescribed in replacement of an oral steroid product and your condition gets worse, you develop a severe infection, you are injured or if you are going to have an operation you should talk to your doctor before using it. They may prescribe a short course of treatment with an oral anti-inflammatory steroid in addition to the nasal spray. During this change over from an oral steroid to this nasal spray you may develop allergic reactions including skin rashes or a runny nose. These reactions may have been disguised by your previous medication. You should consult your doctor.

Other medicines and Beclometasone Dipropionate Aqueous Nasal Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may increase the effects of Beclometasone Dipropionate Aqueous Nasal Spray 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is a very small risk of abnormalities in babies whose mothers have taken Beclometasone Dipropionate during pregnancy. You should discuss with your doctor whether you should take this medicine during pregnancy. They may advise you to take the lowest dose that will control your symptoms for a short period of time. Similarly, this medicine may be passed on to babies through breast milk by mothers taking Beclometasone Dipropionate Aqueous Nasal Spray. You should discuss with your doctor using this medicine while you are breast-feeding.

Driving and using machines

Using Beclometasone Dipropionate Aqueous Nasal Spray should not affect your ability to drive or operate machinery. If however, you do feel affected when you have taken this medicine, you should not drive or operate machinery until you feel better.

Beclometasone Dipropionate Aqueous Nasal Spray contains benzalkonium chloride

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. HOW TO USE BECLOMETASONE DIPROPIONATE AQUEOUS NASAL SPRAY

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Maximum benefit is produced after a few days of regular use. This medicine should be used regularly to maintain its efficacy. Your dose may be altered by your doctor when your symptoms have improved. Do not use this medicine in children under 6 years of age.

Adults and children over 6 years of age:

Recommended dose: 2 sprays (equivalent to 100 micrograms) into each nostril twice a day. Do not take more than 8 sprays (4 sprays per nostril) or 400 micrograms (200 micrograms per nostril) in any 24 hour period.

Long term use of topical corticosteroids should be avoided.

If you use high doses of Beclometasone Dipropionate Aqueous Nasal Spray

There are times when your doctor may need to adjust the dose of the steroid you are given or the way in which you take it. These times are:

- times of extreme stress
- during admission to hospital after a serious accident, injury or illness
- before and after a surgical operation.

If you think that any of these apply to you whilst using Beclometasone Dipropionate Aqueous Nasal Spray, speak to your doctor or pharmacist.

How to Use Beclometasone Dipropionate Aqueous Nasal Spray

Each spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray.

A new spray (or one that has not been used for a few days), may not work first time. You need to 'prime' the spray by pumping the spray a few times until a fine mist is produced.

1. Hold the bottle upright, and make sure it is pointed away from you
2. Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle

3. Keep your thumb still, and press down with your fingers to pump the spray. You may need to do this 4-5 times.

If the spray does not work and you think it may be blocked, you will need to clean it. Please see the section, **Cleaning your spray**.

Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object. This will damage the way the spray works.

Using your spray

1. Shake the bottle vigorously up and down and take off the dust cap.
2. Holding the spray away from your nostril breathe out through your nose.
3. Close one nostril with your finger and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright.
4. Start to breathe in slowly through your nose. While you are breathing in press down firmly on the collar with your fingers. A spray of fine mist will go into your nostril.
5. Remove the nozzle from your nostril and slowly breathe out through your mouth.
6. Repeat step 4 to use a second spray in the same nostril.
7. Remove the nozzle from this nostril and breathe out through your mouth.
8. Repeat steps 3 to 6 for your other nostril.
9. After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief, and replace the dust cap.

Cleaning your spray

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

1. Take the dust cap off.
2. Pull upwards on the white collar to remove the nozzle.
3. Soak the nozzle and dust cap in warm water for a few minutes.
4. Then rinse under a running tap.
5. Shake off the excess water and let them dry in a warm place.
6. Put the nozzle back on the spray.
7. You need to 'Prime' the bottle as described in the section above before using again.

If you use more Beclometasone Dipropionate Aqueous Nasal Spray than you should

Tell your doctor if you use more than you were told to. 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 forget to use Beclometasone Dipropionate Aqueous Nasal Spray

If you have forgotten to take a dose, this should not be a problem. Skip the missed dose and take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose. If you have trouble remembering when to take your medicine, tell your doctor or pharmacist.

If you stop using Beclometasone Dipropionate Aqueous Nasal Spray

Do not stop using Beclometasone Dipropionate Aqueous Nasal Spray even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Severe allergic reactions may occur rarely. The signs may include swelling of your face or throat, shortness of breath or wheezing and skin rashes. **If this happens, tell your doctor straight away you may need urgent medical treatment.**

Immediately after you use your spray

- You may sneeze a little, but this will quickly stop
- Very occasionally you may find you get an unpleasant taste or smell.

Tell your doctor as soon as possible if you notice any of the following side effects:

- Common (may affect up to 1 in 10 people)
- A dry or painful nose or throat
- Bad nose bleeds

- Mild allergic reactions including skin rashes or redness, itching or weals like nettle rash or hives.

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

- Damage to your nose
- Cloudy lens in the eye (cataract)
- Increased pressure in the eye (glaucoma).

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

- Blurred vision (see Section 2).

Very rarely, the normal production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms. In children this side effect can rarely cause them to grow more slowly than others. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. You can also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE BECLOMETASONE DIPROPIONATE AQUEOUS NASAL SPRAY

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package. Do not refrigerate.

Stop using this bottle three months after you first opened it.

If you are told to stop taking this medicine return any unused spray to your pharmacist to be destroyed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Beclometasone Dipropionate Aqueous Nasal Spray contains

Each spray contains 50 micrograms of beclometasone dipropionate.

The other ingredients are: anhydrous glucose, microcrystalline cellulose, sodium carboxymethylcellulose, polysorbate 80, phenylethyl alcohol, benzalkonium chloride solution and purified water.

What Beclometasone Dipropionate Aqueous Nasal Spray looks like and contents of the pack

Beclometasone Dipropionate Aqueous Nasal Spray is an aqueous suspension used for intranasal inhalation via a metered dose atomising pump.

Beclometasone Dipropionate Aqueous Nasal Spray is available in a glass or HDPE vial fitted with a metering pump and nasal applicator. They are provided in packs of 1.

Marketing Authorisation Holder

Ennogen Pharma Limited
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

Manufacturer

Lagap Pharmaceuticals Limited
Woolmer Way, Bordon
Hampshire, GU35 9QE
United Kingdom

This leaflet was last revised in May 2019.

