



PACKAGE LEAFLET: INFORMATION FOR THE USER

**PREVENTER**

**Pulvinal Beclometasone Dipropionate 100** micrograms/metered dose inhalation powder

**Pulvinal Beclometasone Dipropionate 200** micrograms/metered dose inhalation powder

**Pulvinal Beclometasone Dipropionate 400** micrograms/metered dose inhalation powder

beclometasone dipropionate

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet: You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Pulvinal Beclometasone Dipropionate is and what it is used for
2. Before you use Pulvinal Beclometasone Dipropionate
3. How to use Pulvinal Beclometasone Dipropionate
4. Possible side effects
5. How to store Pulvinal Beclometasone Dipropionate
6. Further information

**1. What Pulvinal Beclometasone Dipropionate is and what it is used for**

Pulvinal Beclometasone Dipropionate inhalation powder is used to help prevent the symptoms of asthma. The active ingredient, beclometasone dipropionate, is one of a group of medicines called corticosteroids which are often referred to simply as steroids. Steroids have an anti-inflammatory action reducing the swelling and irritation in the walls of the small air passages in the lungs, and so ease breathing problems.

**2. Before you use Pulvinal Beclometasone Dipropionate**

**Do not use Pulvinal Beclometasone Dipropionate:**

- if you are allergic to beclometasone dipropionate or any of the other ingredients contained in your inhaler
- to treat a sudden attack of breathlessness. It will not help. Use a quick-acting 'reliever' inhaler for this purpose and carry it with you at all times.

**Take special care with Pulvinal Beclometasone Dipropionate and always tell your doctor if:**

- you are being, or have ever been, treated for tuberculosis (TB).
- your asthma seems to be getting worse. Perhaps you are more wheezy and short of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your 'reliever' inhaler than usual, or you do not seem to be getting better. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets, or change your treatment altogether. If you have an infection in your chest your doctor may prescribe a course of antibiotics.
- when transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel a bit poorly or generally unwell, you develop a rash, eczema or a runny nose and sneezing (rhinitis). **Do not stop** treatment with your inhaler unless your doctor tells you to.

If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. For example, during admission to hospital after a serious accident, before an operation, during an acute attack of asthma or if you have a chest infection or other serious illness. Your doctor will decide if you need any extra steroid treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.

If you are using Pulvinal Beclometasone Dipropionate instead of, or as well as taking steroid tablets, or if your doctor is trying to reduce the dose of your steroid tablets, you should carry a steroid warning card until your doctor tells you that you don't need to.

**Taking other medicines:**

Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to take these medicines and your inhalers with you if you have to go into hospital.

In particular tell your doctor if you are taking:

- ketoconazole or itraconazole, to treat fungal infections
- nelfinavir or ritonavir, to treat HIV infection

**Pregnancy and breast-feeding:**

If you are pregnant or breast-feeding, or could become pregnant, talk to your doctor before using your inhaler.

**Important information about some of the ingredients of Pulvinal Beclometasone Dipropionate:**

Pulvinal Beclometasone Dipropionate contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.

**3. How to use Pulvinal Beclometasone Dipropionate**

Pulvinal Beclometasone Dipropionate is available in 3 different strengths. Your doctor will have decided which strength you need.

Always use your inhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Instructions for using your inhaler are given after the dosage section. It takes a few days for your inhaler to work. It is very important that you use it regularly.

**Do not stop** treatment even if you feel better unless told to do so by your doctor.

**Do not stop** using your inhaler abruptly.

While you are using Pulvinal Beclometasone Dipropionate your doctor will want to check your asthma regularly by carrying out simple breathing tests and may need to carry out blood tests from time to time.

**Dosage:**

The starting dose will depend on how severe your asthma is and will be decided by your doctor. Your doctor will prescribe the lowest dose of Pulvinal Beclometasone Dipropionate that will control your symptoms.

**For Adults**

The usual starting dose is 200 to 400 micrograms of Pulvinal Beclometasone Dipropionate each day. If your asthmatic condition require higher doses, your doctor may prescribe 800 to 1600 micrograms of Pulvinal Beclometasone Dipropionate each day. The maximum dose is 2000 micrograms of Pulvinal Beclometasone Dipropionate each day.

**For Children over the age of 6 years**

The usual starting dose is 100 micrograms of Pulvinal Beclometasone Dipropionate 2 to 4 times a day. The maximum dose is 400 micrograms of Pulvinal Beclometasone Dipropionate each day.

**If you use more Pulvinal Beclometasone Dipropionate than you should:**

Tell your doctor as soon as possible. Your doctor may want to check the cortisol levels in your blood and therefore, may need to take a blood sample (cortisol is a steroid hormone which occurs naturally in the body).

It is important that you take your dose stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

**If you forget to use Pulvinal Beclometasone Dipropionate:**

If you forget to use your inhaler, miss out your forgotten dose and take the next dose when it is due. Do not take more puffs than you were told to take.

Please read the back of this leaflet

**Instructions for use:**

It is important that you know how to use your inhaler properly. Your doctor, nurse or pharmacist will show you how to use your inhaler correctly and will check regularly that you are using your inhaler correctly. You must follow their instructions carefully, so that you know **how, when and how many** puffs to inhale and how often you must use your inhaler. The instructions should be on the pharmacist's label and are given in this leaflet. If you are not sure what to do or have problems inhaling then ask your doctor, nurse or pharmacist for advice.

**Do not remove the cap protecting the inhaler until the moment of use.**

**A. Opening**

1. Unscrew the protective cap. Check that the mouthpiece is clean before use. If necessary, wipe the mouthpiece with a fibre-free tissue or soft cloth. Hold the inhaler upright and tap it gently against a hard surface to level the powder in the container.

**B. Loading of the dose**

2. Hold the inhaler upright, press the dark brown button on the mouthpiece with one hand and with the other hand rotate the inhaler **anti-clockwise** through 180 degrees until a red mark shows through the hole in the mouthpiece. This is the loading position.

**C. Administration**

3. Keep holding the inhaler upright, and rotate the inhaler **clockwise** through 180 degrees until it makes a click and a green mark shows through the hole in the mouthpiece. This is the dose-delivery position.
4. Breathe out deeply (not through the inhaler) as far as is comfortable.
5. Put the inhaler between your lips while holding the inhaler upright and breathe in through your mouth as quickly and deeply as possible. Hold your breath for a few seconds.

**D. Closing**

6. Remove the inhaler from your mouth. Replace the protective cap.

**General Advice:**

- Always keep the inhaler upright during the loading of the dose and administration steps.
- If you have been told by your doctor to take a **second puff**, you must **repeat Steps 2 and 3** above, before taking a second puff.
- **How will you know when your inhaler is empty?** When you can see a red ring at the bottom of the container, your inhaler should be replaced. If you continue to use your inhaler when you can see the red ring you may not get the correct dose that has been prescribed for you.
- When you have finished using Pulvinal, check that the hole in the mouthpiece is placed over the green mark. Then close the inhaler.
- If you can feel a slightly sweet tasting powder in your mouth after inhaling you have received the dose and the active substance has reached your lungs.
- The inhaler base contains a desiccant capsule to keep the powder inside your inhaler dry. Always **replace the inhaler cap after you have used the inhaler**. If, however, you leave the inhaler cap off for short periods (e.g. 24 hours) at room temperature, it is still alright to use the inhaler.
- If you accidentally blow into the inhaler, simply hold the inhaler upside down and tap it onto a hard surface to empty the powder out of the dosage chamber. If you think you may have accidentally loaded two or more doses into the chamber, hold the inhaler upside down and tap it on a hard surface to empty the powder out.
- During use, regularly wipe the mouthpiece with a fibre-free tissue or soft cloth.

**4. Possible side effects**

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

**If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straightaway.**

- if your breathing or wheezing gets worse straight after using your inhaler
- allergic reaction (affects less than 1 in 100 people) - the signs include rashes, itching, redness of the skin, weals like nettle rash or hives and bruising
- severe allergic reaction (affects less than 1 in 10,000 people) - the signs include swelling of the mucous membrane especially of eyes, lips or throat which may cause difficulty in breathing.

Your doctor will review your asthma and may change your treatment and may prescribe a different inhaler to treat your asthma.

The following side effects have been reported. Tell your doctor as soon as possible if you suffer from any of these side effects but **do not stop** treatment unless told to do so. Your doctor will try to prevent these effects by prescribing Pulvinal Beclometasone Dipropionate in the lowest dose possible to control your asthma.

**Very common** (affecting more than 1 in 10 people):

- thrush in the mouth and throat. This is more likely if the daily dose taken is high. Thrush can be treated with anti-fungal medicine whilst you continue to use Pulvinal Beclometasone Dipropionate. Brushing your teeth or thoroughly rinsing your mouth with water immediately after each dose may help prevent thrush.

**Common** (affecting less than 1 in 10 people):

- hoarseness, sore throat

**Very rare** (affecting less than 1 in 10,000 people):

- a round, puffy face (called "moon face")
- weight gain, especially on the neck and shoulders
- shortness of breath

**Using high-dose inhaled corticosteroids over a long time can cause, in very rare cases, systemic effects.** These include:

- decrease in bone mineral density (thinning of the bones)
- growth retardation (slowing of growth) in children and adolescents. Your doctor may wish to check the height of your children regularly
- increase pressure in your eyes (glaucoma)
- cataract
- lower respiratory tract infection
- problems with how your adrenal glands work (adrenosuppression) - causing loss of appetite, abdominal pain, weight loss, tiredness, feeling sick, being sick, feeling faint, sweating and possible fits, you should consult your doctor. This is particularly important if you have been exposed to stress such as surgery, infection, an acute attack of asthma, or other serious illness. Your doctor may carry out blood test from time to time to monitor the level of steroids in your body.

**Frequency not known:**

- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. How to store Pulvinal Beclometasone Dipropionate**

- **Keep out of the reach and sight of children.**
- Do not use Pulvinal Beclometasone Dipropionate after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep the container tightly closed.
- Always replace cap after use.
- 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 Pulvinal Beclometasone Dipropionate contains**

The active substance of your inhaler is beclometasone dipropionate. Each puff contains 100, 200 or 400 micrograms of beclometasone dipropionate. The other ingredients are lactose monohydrate and magnesium stearate.

**What Pulvinal Beclometasone Dipropionate looks like and content of the pack**

Pulvinal Beclometasone Dipropionate is an inhalation powder contained in a multi-dose container with plastic mouthpiece and protective cap. Each pack contains one inhaler which provides 100 puffs.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder of Pulvinal Beclometasone Dipropionate is Chiesi Limited, Cheadle Royal Business Park, Highfield, Cheadle, SK8 3GY, UK. The manufacturer of Pulvinal Beclometasone Dipropionate is Chiesi Farmaceutici S.p.A., 26/A Via Palermo, 43100 Parma, Italy.

**Is this leaflet hard to see or read?**

**Phone 0161 488 5555 for help.**

The leaflet was last approved in 04/2011

CP0019/3