

Pulvinal® Salbutamol 200 micrograms per metered dose inhalation powder

salbutamol

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 Salbutamol is and what it is used for
2. Before you use Pulvinal Salbutamol
3. How to use Pulvinal Salbutamol
4. Possible side effects
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6. Further information

1. What Pulvinal Salbutamol is and what it is used for

Pulvinal Salbutamol inhalation powder is used to help **relieve** the symptoms of mild, moderate and severe asthma, other chest illnesses and to avoid asthma symptoms brought on by exercise or other 'triggers'. Common 'triggers' include pollen, cigarette smoke, house dust, cats and dogs.

The active ingredient, salbutamol, is one of a group of medicines called bronchodilators or '**relievers**'. Salbutamol relaxes the muscles in the walls of the small air passages in the lungs. This helps to open up the airways and so helps to relieve chest tightness, wheezing and cough so that you can breathe more easily.

2. Before you use Pulvinal Salbutamol

Do not use Pulvinal Salbutamol:

- if you are allergic to salbutamol or any of the other ingredients contained in your inhaler
- to treat premature labour or a threatened miscarriage.

Take special care with Pulvinal Salbutamol and always tell your doctor if:

- you suffer from an over active thyroid gland
- your asthma seems to be getting worse. Perhaps you are more wheezy or short of breath than usual, your inhaler seems to be less effective, you require more puffs from your inhaler than usual, or you do not seem to be getting better. Your doctor will re-assess your asthma and may change your treatment or give you an extra medicine.
- you suffer from any disease of the heart or if your symptoms appear to be getting worse
- you experience chest pains

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:

- beta-blockers (such as propranolol) or water tablets (diuretics), used to treat high blood pressure or a heart condition
- theophylline, aminophylline or steroids, used to treat asthma.
- antidepressants, particularly monoamine oxidase inhibitors

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 Salbutamol

Pulvinal Salbutamol 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 Salbutamol

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. **Do not stop** using your inhaler unless told to do so by your doctor.

Pulvinal Salbutamol must be used for the **relief** of your asthma symptoms only. You may have other medicines which you take regularly to **prevent** the symptoms of your asthma.

While you are using Pulvinal Salbutamol 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 (see also Section 4 - Possible side effects).

Dosage**Adults, adolescents aged 12 years and over, and children 4 to 11 years of age**

Take one puff (200 micrograms), for the relief of asthma symptoms such as wheezing or shortness of breath.

To avoid the symptoms of asthma brought on by exercise or other 'triggers', such as pollen, cigarette smoke, house dust, cats and dogs, take one puff (200 micrograms) 10-15 minutes before exercise or exposure to a 'trigger'.

After taking a puff, you must wait for four hours before taking another puff.

Do not take more than 4 puffs (800 micrograms) in any 24 hour period.

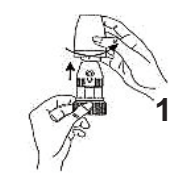
If you use more Pulvinal Salbutamol than you should

If you accidentally take more puffs than you should, you may notice that your heart is beating faster than usual and that you feel shaky. These effects usually disappear after a few hours, but you must tell your doctor as soon as possible.

Instructions for use

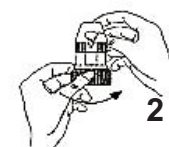
It is important that you know how to use your inhaler properly. Your doctor, nurse or pharmacist will show you how to use your inhaler correctly and will check regularly that you are using your inhaler correctly. You must follow their instructions carefully, so that you know **how, when** and **how many** 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.



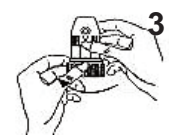
A. Opening

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 the dose

2. Hold the inhaler upright, press the blue 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.



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.

C. Administration

4. Breathe out deeply (not through the inhaler) as far as is comfortable.



5. Put the inhaler between your lips, keep 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.
- **How will you know when your inhaler is empty?** When you can see a red ring at the bottom of the container your inhaler needs to 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 Salbutamol can cause side effects, although not everybody gets them.

Very rare allergic reactions, including nettle rash or hives, wheezing, fall in blood pressure, collapse or painless swelling of the skin on the face, neck, hands, feet and lips have been reported. If you experience any of these, contact your doctor or casualty department immediately.

If your breathing or wheezing gets worse straight after using your inhaler, stop using Pulvinal Salbutamol and contact your doctor straightaway. Your doctor will review your asthma and may change your treatment and may prescribe a different inhaler to treat your asthma.

Abnormally **low levels of potassium** in the blood (hypokalaemia) can be caused by regular use of 'reliever' inhalers, such as Pulvinal Salbutamol. The low levels of potassium, which can cause you to feel weak and thirsty, can worsen during an acute asthma attack. Therefore, while you are using Pulvinal Salbutamol your doctor may need to carry out blood tests from time to time.

Throat irritation or cough sometimes occurs if you are sensitive to inhaling a dry powder. Rinsing your mouth after inhalation may help prevent this.

The following side effects have also 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:

Common (affects less than 1 in 10 people)

- feeling shaky
- headache

Uncommon (affects less than 1 in 100 people)

- feeling your heartbeat

Rare (affects less than 1 in 1,000 people)

- hyperactivity in children
- increased blood flow to your extremities
- muscle cramps

Very rare (affects less than 1 in 10,000 people)

- irregular heartbeat or an extra beat of the heart
- rapid heartbeats with or without flushing

Unknown

- feeling nervous
- restriction of bloodflow to the heart
- dizziness

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

5. How to store Pulvinal Salbutamol

- **Keep out of the reach and sight of children.**
- Do not use Pulvinal Salbutamol 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 the 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 Salbutamol contains

The active substance of your inhaler is salbutamol. Each puff contains 200 micrograms of salbutamol. The other ingredient is lactose monohydrate.

What Pulvinal Salbutamol looks like and contents of the pack

Pulvinal Salbutamol 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 Salbutamol is Chiesi Ltd, Cheadle Royal Business Park, Highfield, Cheadle, SK8 3GY, UK.

The manufacturer of Pulvinal Salbutamol 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.

This leaflet was last revised in 06/2012

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Pulvinal® is a trade mark of the same patented Chiesi DPI.

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