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
5. How to store Pulvinal Salbutamol
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 overactive 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 propanolol) 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 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.

Please read the back of this leaflet
What Pulvinal Salbutamol looks like and content of the pack

Pulvinal Salbutamol is an inhalation powder contained in a multi-dose container with plastic mouthpiece.

- During use, regularly wipe the mouthpiece with a fibre-free tissue or soft cloth.
- If you accidentally blow into the inhaler, simply hold the inhaler upside down.
- If you can feel a slightly sweet tasting powder in your mouth after inhaling, you have not activated 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 cannot feel a slight sweet taste of the powder, rinsing your mouth after inhalation may help prevent this.

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 on the right mark. Then close the mouthpiece.
- If you can feel a slightly sweet tasting powder in your mouth after inhaling, you have not activated 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 cannot feel a slight sweet taste of the powder, rinsing your mouth after inhalation may help prevent this.

Instructions for use

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 tip gently against a hard surface to level the powder in the container.

2. Loading the dose

3. Keep holding the inhaler upright, and rotate the inhaler clockwise through 180 degrees until a red mark shows through the hole in the mouthpiece. This is the loading position.

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

5. Put the inhaler between your mouth, keep holding the inhaler upright and breathe in through your mouth as quickly and deeply as possible. Hold your breath for a few seconds.

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

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, swelling of the face, neck, hands or feet have been reported. If you experience any of these, contact your doctor or pharmacist 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 another 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 advise you to take potassium tablets or a salt substitute.

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 nervous
  - headache

- Uncommon (affects less than 1 in 100 people)
  - feeling heart beat

- Rare (affects less than 1 in 1,000 people)
  - hyperactivity in children
  - increased blood flow to your extremities
  - muscle cramps

- Unknown

- feeling nervous
- redness or blood flow to the heart
- dizziness

If any of these 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 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 medicines may help to protect the environment.

Further information

What Pulvinal Salbutamol contains

The active ingredient of Pulvinal Salbutamol is salbutamol. Each pack contains 200 micrograms of salbutamol.

What Pulvinal Salbutamol looks like and contents of the pack

Pulvinal Salbutamol is supplied as an inhalation powder in each 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 Farmaceutici S.p.A., 26/A Via Palermo, 43100 Parma, Italy.

Pulvinal® is a trademark of the same patented Chiesi DPI.

If this leaflet is hard to see or read? phone 0161 489 5555 for help.