Package leaflet: Information for the user

Pulmicort 0.25 mg/ml and 0.5 mg/ml, nebulising suspension
budesonide

Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pulmicort is and what it is used for

Pulmicort is used in regular treatment of asthma.

Pulmicort relieves and prevents inflammation in the airways caused by asthma.
Pulmicort is intended for regular and maintenance use and not for rapid relief of acute asthma conditions. It may take some weeks before you receive the full effect of the treatment.

Pulmicort can also be used in hospitals treating very serious pseudocroup (laryngeal inflammation that can cause breathing difficulties).

2. What you need to know before you use Pulmicort

Do not use Pulmicort
- if you are allergic to budesonide or any of the other ingredients in this medicine (see section 6).

Take special care with Pulmicort
Tell your doctor if you:
- have or have had a liver disease or a problem with your liver,
- have lung tuberculosis (active or inactive),
- have a fungal or viral infection in the airways.

If you switch from cortisone tablets to Pulmicort, your previous allergic symptoms such as a runny nose and eczema may return in certain cases. You may also experience tiredness, headaches, muscle and joint pain and occasionally nausea and vomiting. This is because the total amount of cortisone in the body is reduced when the disease is treated locally in the lungs. These symptoms disappear after you have received treatment for some time.

You should rinse your mouth out with water after each dosage to minimise the risk of fungal infection in your mouth and throat. Contact your doctor if you get symptoms of a fungal infection.

In rare cases, in long term treatment with budesonide, growth in children and adolescents may reduce. If your child uses this medicine for a long time, the doctor will usually want to check the child's height regularly.

You must contact your doctor if your asthma gets worse. This may mean that the dosage needs to be changed or that you need other treatment.

In an acute asthma attack you must use your fast-acting asthma medicine.

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

Children and adolescents
The doctor will regularly monitor the height of children who are receiving prolonged treatment with Pulmicort. If growth is slowed, therapy should be re-evaluated.

Other medicines and Pulmicort
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines may affect or be affected by treatment with Pulmicort, for example those containing:
- ketoconazole or itraconazole (present in medicines for fungal infections).
- saquinavir, indinavir, ritonavir, nelfinavir, amprenavir, lopinavir, fosamprenavir, atazanavir or tipranavir (known as HIV protease inhibitors that are used in HIV).

Pulmicort may affect a test that is made to check pituitary function, ACTH simulation test, which may give a false low value.

Pregnancy and breast-feeding
Experience from usage during pregnancy does not show any increased risk of malformations. However, you must talk to your doctor before using Pulmicort during pregnancy because the severity of the asthma may change and the treatment may need to be adjusted.

Budesonide is excreted in breast milk. However, no effects on the nursing child are anticipated with therapeutic doses of Pulmicort. Pulmicort can be used during 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.

Driving and using machines
Pulmicort does not affect your ability to drive a car or use machines.

3. How to use Pulmicort

Always use Pulmicort exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor prescribes the correct dose for you.
The number of doses varies according to the severity of your asthma.
You must use Pulmicort regularly, i.e. every day, even if you have no symptoms.

Pulmicort nebulising suspension is inhaled via a nebuliser device (= inhaler). When you breathe in through the mouthpiece or the facemask, the medicine follows the inhaled air into your airways. Therefore, it is important to breathe in smoothly and calmly when you take your dose, see the "Instructions for use".

Instructions for use
Pulmicort nebulising suspension must only be used in a special inhaler called a nebulisator.

1. Mix the suspension before use by carefully shaking the single dose unit in a circular motion.

2. Hold the single dose unit upright and open by twisting off the wing.

3. Squeeze out the liquid into the nebuliser chamber.

The single dose unit is marked with a line. This line indicates a volume of 1 ml when the single dose unit is held upside down.
If only 1 ml is to be used, empty the contents until the level of the liquid reaches the indicator line.

Store the opened single dose unit away from light.
The opened single dose unit must be used within 12 hours.
Shake the single dose unit carefully before using the remaining liquid.

Since the nebuliser chamber always contains 2 ml prior to opening, you must dilute it with salt solution (or mix it with another liquid for the nebuliser if your doctor has told you to) if you are to inhale only 1 ml of Pulmicort nebulising suspension.

When you inhale, it is important to breathe in smoothly and calmly via the mouthpiece of the nebulisator. A facemask could be used to make it easier for a child to breathe in.

Rinse your mouth with water after each dose to get rid of any medicine remaining in your mouth.
If a facemask is used, make sure that it fits tightly while you are inhaling and wash your face afterwards.

Cleaning
Clean the nebuliser chamber and the mouthpiece or facemask in hot water using a mild detergent after each dose. Rinse well and dry.

For further information, read the recommendations from the manufacturer of the nebulisator.

If you take more Pulmicort than you should
If you have taken a larger dose than your doctor has prescribed on one occasion, you will probably not suffer from any side effects. However, if you use a larger dose than your doctor has prescribed over a longer period of time (months), there is a risk that you will suffer from side effects.

If you took too great a quantity of medicine or for example a child took the medicine by mistake, contact your doctor, hospital or the Poison Information Centre for evaluation of about the risk and advice.

It is important that you take the dose stated on the label of the packaging or as your doctor has told you. Do not increase or decrease the dose without contacting your doctor.

If you forget to take Pulmicort
If you have forgotten to take one dose, take the next dose as usual.

4. Possible side effects

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

Serious side effects
Common (up to 1 of 10 users might be affected): pneumonia (infection of the lung) (in COPD patients).

Tell your doctor if you have any of the following while taking Pulmicort as they could be symptoms of a lung infection:
- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties.

Rare (up to 1 of 1000 users might be affected): angioedema, anaphylactic reactions, bronchospasm (contraction of the airway muscles).

Stop taking Pulmicort and contact your doctor immediately if you get any of the following symptoms of angioedema:
- swelling of the face, tongue or throat
- difficulties to swallow
- hives and breathing difficulties.

Other possible side effects
Common (up to 1 of 10 users might be affected): Irritation of the throat, coughing, fungal infection in the mouth cavity and throat.

Uncommon (up to 1 in 100 users might be affected): Cataract (clouding of the lens in the eye), blurred vision, depression, anxiety, muscle spasm, tremor.

Rare (up to 1 of 1000 users might be affected): Immediate and delayed hypersensitivity reactions including hives and other skin rashes, contact dermatitis and corticosteroid effects (see below). Bruising, dysphonia (difficulties to speak), hoarseness, restlessness, agitation, behavioural changes (occur mainly in children).

The following have been reported (occur in an unknown number of users): Glaucoma (increased pressure in the eye), sleep disturbances, aggression, feeling of being very upset and/or irritable.

Irritation of skin on the face has been reported in some cases when the facemask has been used. To avoid this you must always wash your face after using the facemask, see the "Instructions for use".

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:
- Changes in bone mineral density (thinning of the bones).
- Cataract (clouding of the lens in the eye).
- Glaucoma (increased pressure in the eye).
- Decreased growth rate in children and adolescents.
- An effect on the adrenal gland (a small gland next to the kidney).

These effects are much less likely to happen with inhaled corticosteroids than with cortisone tablets.

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 this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Läkemedelsverket
Box 26
751 03 Uppsala
www.lakemedelsverket.se

5. How to store Pulmicort

- Store the single dose units in a closed foil envelope. Sensitive to light.
- Do not store above 30°C. Do not freeze..
- Single dose units in an opened foil envelope should be used within 3 months.
- Opened single dose units must be used within 12 hours. Note: If only 1 ml has been used, the remaining volume is not sterile.
- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date that is stated on the package (EXP). The expiry date refers to the last day of that month.
- 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.
- Shelf-life is 2 years.

6. Contents of the pack and other information

What Pulmicort contains
- The active substance is budesonide. One single dose unit (2 ml) contains 0.5 mg or 1 mg budesonide, respectively.

- The other ingredients are edetate disodium, sodium chloride, polysorbate 80, citric acid (anhydrous), sodium citrate and water for injection. These ingredients are excipients that help make up the suspension.

What Pulmicort looks like and contents of the pack
Each pack (20 x 2 ml) contains 4 foil envelopes with 5 single dose units containing 2 ml each.

Marketing Authorisation Holder and Manufacturer
AstraZeneca AB, 151 85 Södertälje, Sweden.

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