

PULMICORT®

Budesonide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions ask about Pulmicort. It does not contain all the information that is known about Pulmicort.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pulmicort against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PULMICORT is used for

Pulmicort is inhaled into the lungs for the treatment of asthma. Asthma is a disease where the airways of your lungs become

narrow and inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke, air pollution or other things that irritate your lungs.

Pulmicort contains budesonide. This belongs to a family of medicines called corticosteroids, which are used to reduce inflammation in many parts of the body.

Pulmicort acts directly on your airways to reduce inflammation. This helps to improve your condition and to prevent asthma attacks from occurring.

It is a "preventer" and needs to be taken regularly.

Pulmicort may also be used to treat croup in infants and children.

Ask your doctor if you have any questions about why Pulmicort has been prescribed for you.

Your doctor may prescribe it for another reason.

Pulmicort is not addictive.

Pulmicort is available only with a doctor's prescription.

Before you use PULMICORT

When you must not use it

Do not use Pulmicort if you have an allergy to:

- any medicine containing budesonide
- any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

Do not use Pulmicort after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return to your pharmacist for disposal.

Do not use Pulmicort to treat any other complaints unless your doctor tells you to.

If you are not sure whether you should start using Pulmicort, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of these medical conditions:

- liver problems
- tuberculosis (TB).

It may not be safe for you to take Pulmicort if you have, or have had, any of these conditions.

Tell your doctor if you currently have an infection.

If you take Pulmicort while you have an infection, the medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor if you are pregnant or plan to become pregnant or breastfeeding.

Your doctor will advise you of the risks and benefits of using Pulmicort during pregnancy and while breastfeeding.

If you have not told your doctor about any of the above, tell them before you start using Pulmicort.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Pulmicort may interfere with each other. These include:

- other corticosteroid medicines, such as tablets, asthma inhalers, nasal sprays, or eye/nose drops.
- medicines used to treat fungal infections (such as ketoconazole, itraconazole).

These medicines may be affected by Pulmicort, or may affect how well it works. You may need different amounts of your medicine, or you may need to use a different medicine. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using Pulmicort.

How to use PULMICORT

Pulmicort comes in two different forms:

- the Turbuhaler; or
- Respules (containing nebulising suspension) for use in a nebuliser.

Each package of Pulmicort contains an instruction leaflet that tells you the correct way to use it. Please read it carefully.

If you are not sure how to use the Turbuhaler or Respules, ask your doctor or pharmacist.

ASTHMA - Adult dose

Pulmicort Turbuhaler:

The dose can range from 400 to 2400 micrograms per day, in divided doses (either 2, 3 or 4 times a day).

If you take 400 micrograms or less a day, you may take this as a single daily dose in the morning or evening.

When your asthma is under control, your doctor may tell you to use a lower dose. The usual maintenance dose is 100 to 400 micrograms per day. This may be given as a once or twice daily dose.

Pulmicort Respules:

The dose can range from 1 to 2 mg twice a day.

When your asthma is under control, your doctor may tell you to use a lower dose. The usual maintenance dose is 0.5 to 1 mg twice a day.

ASTHMA - Children's dose:

Children are usually considered to be aged 12 years or less, but check with your doctor if you are at all worried about the dose that has been prescribed for your child.

Children should be 5 years or older before they use the Turbuhaler.

Pulmicort Turbuhaler:

The dose can range from 200 to 800 micrograms per day, in divided doses (either 2, 3 or 4 times a day).

When your child's asthma is under control, the doctor may prescribe a lower dose for your child. The usual maintenance dose is 100 to 400 micrograms per day. This may be given as a once or twice daily dose.

Pulmicort Respules:

The dose can range from 0.5 to 1 mg twice a day.

When your child's asthma is under control, the doctor may prescribe a lower dose for your child. The usual maintenance dose is 0.25 to 0.5 mg twice a day.

CROUP

Pulmicort Respules can also be used to treat croup in infants and children. It will be given as one 2 mg dose of budesonide.

If you forget to use it

If you forget to use your Pulmicort, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (131 126), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Pulmicort. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

Things you must do

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor should give you a personal Asthma Action plan to help manage your asthma. This plan will include medicines to take regularly to control your asthma, eg Pulmicort Turbuhaler, as well as "reliever" medicines to use when you have sudden attacks of breathlessness eg Bricanyl® (terbutaline) Turbuhaler.

If you are using more inhalations of your "reliever" medicine or you are wheezing or breathless more than

usual, please contact your doctor so that your condition can be checked.

This is important to ensure your breathing problem is controlled properly.

Continue using Pulmicort for as long as your doctor tells you to, even if you feel better.

Pulmicort helps control your condition. Therefore you must use it every day.

See your doctor regularly to make sure that your asthma is not getting worse.

Your doctor may change your dose of Pulmicort (up or down) depending on your condition.

Tell any other doctors, dentists and pharmacists who are treating you that you are using Pulmicort.

If you are about to be started on a new medicine, tell your doctor or pharmacist that you are using Pulmicort.

If you become pregnant while using Pulmicort, tell your doctor or pharmacist.

Be sure to rinse your mouth out with water after every time you use Pulmicort.

If you do not rinse your mouth, you are more likely to develop thrush in the mouth.

Be sure to wash your face after each use of Pulmicort Respules.

If you do not wash your face you might get irritation of the skin.

Things you must not do

Do not stop using Pulmicort for your asthma without checking with your doctor.

Do not use Pulmicort to treat any other complaints unless your doctor tells you to.

Do not give Pulmicort to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Pulmicort.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- sore, yellowish, raised patches in the mouth (thrush)

- hoarse voice
- irritation of the tongue and mouth

These are less likely to happen if you rinse your mouth out after every time you use Pulmicort.

- dry mouth
- unpleasant taste in your mouth
- cough
- irritation of the throat
- thirsty
- headache
- light-headedness
- tiredness
- feeling nervous or restless
- nausea
- diarrhoea
- weight gain
- skin rash
- skin bruising.

These side effects are usually mild.

Tell your doctor or pharmacist immediately if you notice any of the following:

- difficulty breathing or worsening of your breathing problems
- swelling of the face, lips, tongue or other parts of the body
- severe rash
- mood changes (such as depression).

These may be serious side effects. You may need urgent medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice any issues with your eyes such as blurred vision or other problems with your eyesight.

Your doctor may need to send you to an ophthalmologist (eye doctor) to check that you don't have eye problems such as cataracts (clouding of the eye lens), glaucoma (increased pressure in your eyeballs) or other rare eye conditions reported with corticosteroid use.

Your adrenal glands may be affected by taking high doses of corticosteroids over a long period of time or if you change

from or use high doses of oral corticosteroids. Your doctor may do tests to check how the adrenal glands are working.

Your doctor may also tell you to take additional oral corticosteroids during periods of stress such as trauma, surgery and infection.

Corticosteroids taken into the lungs for long periods (eg 12 months) may affect how children grow. In rare cases, some children may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's height.

Ask your doctor to answer any questions you may have.

After using it

Cleaning

The Turbuhaler must be wiped with a clean dry tissue and must never get wet.

Full instructions on the right way to use and clean the Turbuhaler are inside the pack.

Storage

Keep your Pulmicort Turbuhaler in a cool dry place where the temperature stays below 30 degrees C, with the cover firmly in place.

Keep Pulmicort Respules protected from light by keeping them in the foil envelopes and in a cool dry place where the

temperature stays below 30 degrees C. Do not refrigerate or freeze.

Unused, unopened Respules should be discarded 3 months after opening the foil pack.

Do not store Pulmicort or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Pulmicort, or it has passed its expiry date, ask your pharmacist what to do with any you have left over.

Product description

Pulmicort Turbuhaler contains budesonide as the active ingredient in strengths of 100 micrograms, 200 micrograms or 400 micrograms per dose.

Each Turbuhaler contains 200 doses (inhalations). The Turbuhaler is made of plastic parts.

Pulmicort Respules contain budesonide 0.5 mg / 2 mL or 1 mg / 2 mL as the active ingredient, and the following inactive ingredients:

- Disodium edetate
- Sodium chloride
- Polysorbate 80 (E 433)
- Citric acid (E 330)
- Sodium citrate dihydrate (E 331)
- Water for Injections.

Each box contains 30 Respules with 5 Respules in each silver foil pack.

Supplier

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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Australian Registration Numbers:

Pulmicort Turbuhaler

- 100 micrograms
AUST R 10063
- 200 micrograms
AUST R 10065
- 400 micrograms
AUST R 10064

Pulmicort Respules

- 0.5 mg / 2 mL
AUST R 10072
- 1 mg / 2 mL
AUST R 10071

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