

PULMICORT RESPULES®

Budesonide (0.25mg in 1 ml, 0.5mg in 1 ml)

What is in this leaflet

1. What Pulmicort Respules is used for
2. How Pulmicort Respules works
3. Before you use Pulmicort Respules
4. How to use Pulmicort Respules
5. While you are using it
6. Side effects
7. Storage & Disposal of Pulmicort Respules
8. Product Description
9. Manufacturer & Product Registration Holder
10. Date of Revision
11. Serial Number

What Pulmicort Respules is used for

- Controlling asthma
- Treating croup (a condition making it hard to breathe due to inflammation in the upper airway) in babies and children
- Treating adults with worsening symptoms of chronic obstructive pulmonary disease (COPD)

How Pulmicort Respules works

Pulmicort Respules contains the active ingredient budesonide, which is a corticosteroid. Budesonide works by reducing inflammation of the airways, thus making breathing easier

Before you use Pulmicort Respules

- When you must not use it

Do not use Pulmicort Respules if you are allergic (hypersensitive) to budesonide or any other ingredients of this medicine (listed in the Product Description section).

- Before you start to use it

Tell your doctor before using Pulmicort Respules if you are:

- Currently having a severe asthma attack
- Currently taking oral corticosteroids
- Have tuberculosis or respiratory infections

- Have liver problems

Pregnancy and lactation

If you are pregnant, planning to get pregnant, or think you may be pregnant, discuss with your doctor before starting any medicine.

Budesonide must only be used during pregnancy if the benefits are more than the risks to the foetus.

Budesonide is secreted into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you're using budesonide.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicine that you buy without a prescription from a pharmacy, supermarket, or health food shop.

Tell your doctor or pharmacist if you are taking or using:

- Ketoconazole and itraconazole (anti-fungal medications).
- Medications that inhibit CYP3A4 enzyme that may increase the effects of Pulmicort Respules. Your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).
- Other corticosteroid medicines (oral or inhaled).

How to use Pulmicort Respules

Pulmicort Respules are inhaled using a suitable nebuliser machine. Pulmicort Respules may be nebulised in combination with Bricanyl®, Ventolin™, Intal™, Atrovent™ or normal saline.

The medicine is put into the nebuliser chamber and converted into a mist that is inhaled through a mouthpiece or face mask.

Instructions for Use:

1. Set up your nebuliser for filling.
2. Take 1 Pulmicort Respule.
3. Shake the respule.
4. Twist off the top of the respule.
5. Squeeze the contents into the nebuliser reservoir. Only dilute if your physician instructs.
(Note: Your doctor may advise using only part of the respule content for your prescribed dose).
6. Follow the nebuliser usage instructions, ensuring the reservoir is completely emptied.
7. Clean your nebuliser according to the manufacturer's recommendations after use.

Additional Tips:

- Rinse your mouth with water after each use.
- If using a face mask, wash your face after each use.
- Rinse the nebuliser's mouthpiece or face mask with warm water and let it dry after each session.

Important Information:

- The aerosol mist produced by the nebuliser must be the right size and strength for optimal lung function.
- For Pulmicort Respules, use a compressed air jet nebuliser with an output of at least 6 to 8 litres per minute.
- Check your nebuliser's manual or consult the manufacturer to ensure it meets these requirements.

- How much to use

The dosage is individual. Follow your doctor's instructions carefully. They may differ from the information contained in this leaflet.

Asthma

Adult

- Initial/severe asthma: 1-2 mg twice daily

- Maintenance: 0.5-1 mg twice daily

Children

- Initial/severe asthma: 0.5-1 mg twice daily
- Maintenance: 0.25-0.5 mg twice daily

Croup (in children)

Usual dose: 2 mg as a single dose or as 2 doses of 1 mg (interval 30 minutes between doses).

This can be repeated every 12 hours for up to 36 hours.

Worsening of COPD in adults

4 to 8 mg daily in 2 to 4 divided doses, for up to 10 days.

When to use it

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

- How long to use it

Use Pulmicort Respules for the duration that the doctor recommends. If your condition worsens or you need more inhalation than usual, you should consult your doctor.

You will feel better in 10 days. Continue to use Pulmicort Respules even after you feel a bit better.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Using too much of this medicine may cause low plasma cortisol level and abnormal white blood cells count.

Regularly using too much may result in excessive cortisol and lead to a slowdown in the body's natural stress response system.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using Pulmicort Respules.

Tell your doctor immediately if you become pregnant while using this medication.

Take Pulmicort Respules only with a doctor's prescription.

- Things you must not do

Do not stop using Pulmicort Respules unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not use Pulmicort Respules for rapid relief of symptoms.

Do not swallow or inject the contents of Pulmicort Respules.

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

Do not use ULTRASONIC nebulisers with Pulmicort Respules, as they create vibrations in the liquid that can make the treatment ineffective. Not all nebulisers are suitable for Pulmicort Respules.

- Things to be careful of

- Avoid getting the aerosol into the eyes.
- Rinse your mouth out after each inhalation to prevent mouth and throat yeast infections.
- Pulmicort Respules should be added to the nebuliser immediately before use, not to be mixed in advance.

Driving and using machines

Be careful driving or operating machinery until you know how Pulmicort Respules affects you.

Side effects

Like all medicines, Pulmicort Respules can cause side effects, although not everybody gets them.

Common Side Effects:

- Nose and throat: hoarseness, sore throat, tongue and mouth irritation, dry mouth, oral fungal/ yeast infection
- Respiratory: cough
- Pneumonia (infection of the lung) in COPD patients. Tell your doctor if you have any of the following while taking Pulmicort Respules. They could be symptoms of a lung infection:
 - Fever or chills;
 - Increased mucus production or change in mucus colour;
 - Increased cough or increased breathing difficulties.

Uncommon Side Effects:

- Nose and throat: larynx irritation, bad taste
- Gastrointestinal: diarrhoea, nausea
- Hypersensitivity reactions: skin reactions, tightening of the airway in the lungs, swelling underneath the skin, serious allergic reaction
- Central Nervous System: headache, light-headedness, thirst, tiredness
- Metabolic and nutritional disorders: weight gain
- Eye disorders: blurred vision

Other Side Effects:

- Skin bruising (rare)
- Facial skin irritation
- Mental disorders (behavioural disturbances, nervousness, restlessness and depression)

Inhaled corticosteroids, when used at higher than recommended doses, can affect the normal production of steroid hormones in your body, particularly if used for a long time. The effects include:

- Reduction of bone density or bone mineral loss
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)
- Decreased growth rate in children

- An effect on the adrenal gland (a small gland next to the kidney)

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage & Disposal of Pulmicort Respules

- Storage

- Store below 30°C. Do not refrigerate or freeze.
- Keep respules protected from light during storage. Keep unused respules sealed in the foil envelope that the product comes packaged in.
- After opening the foil package, any unused respules should be discarded after 3 months.
- Check respules before use. Discard if the suspension does not fully resuspend when shaken. Some settling of the medication may occur during storage - this is normal, but it needs to be able to reconstitute.
- Opened single dose respule units may be used for up to 12 hours after opening. But do not store opened respules for reuse - these are intended as a single use product.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

White to off-white suspension in plastic single dose units.

- Ingredients

Active Ingredients

Pulmicort Respules 0.25 mg/ml: Each single-dose unit of 2ml contains 0.5 mg of budesonide.

Pulmicort Respules 0.5 mg/ml: Each single-dose unit of 2ml contains 1 mg of budesonide.

Inactive Ingredients

Disodium edetate, sodium chloride, polysorbate 80 (E 433) citric acid - anhydrous (E 330), sodium citrate (E 331) and water for injections.

- MAL number:

Pulmicort Respules 0.25 mg/ml: MAL19940089AZ

Pulmicort Respules 0.5 mg/ml: MAL19940088ARZ

Manufacturer

AstraZeneca AB
Forskargatan 18,
SE-151 36 Södertälje,
Sweden.

Product Registration Holder

AstraZeneca Sdn. Bhd.
Level 11 & 12, The Bousteador,
No. 10, Jalan PJU 7/6, Mutiara
Damansara, 47800 Petaling Jaya,
Selangor, Malaysia.

Date of revision

07/01/2025
VV-RIM-04945789
(Based on PI - VV-RIM-
01321498)

Serial number

NPRA(R4/1)280224/00024