

Pulmicort® Respules® 1 mg/2 ml Nebuliser 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1 What Pulmicort Respules are and what they are used for

The name of your medicine is Pulmicort Respules 1 mg/2 ml Nebuliser Suspension (called Pulmicort Respules in this leaflet). Pulmicort Respules contain a medicine called budesonide. This belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.

- * Pulmicort Respules are used to treat asthma. They are also used to treat croup in infants and children.
- * A Respule is a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine turns the medicine into a fine mist which you breathe in through a face mask or mouthpiece.

2 What you need to know before you use Pulmicort Respules

Do not use Pulmicort Respules:

- * If you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Pulmicort Respules if:

- * You have or have ever had tuberculosis (TB).
- * You have a cold or chest infection.
- * You have liver problems.
- * You have an infection of the airways.
- * You have any current infections.

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

Other medicines and Pulmicort Respules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Pulmicort Respules can affect the way some medicines work and some medicines can have an effect on Pulmicort Respules and your doctor may wish to monitor you carefully. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- * Steroid medicines.
- * Medicines to treat fungal infections (such as itraconazole and ketoconazole).
- * Medicines used to treat the HIV infection (such as ritonavir or cobicistat-containing products).
- * Medicines that may be used as a form of birth control or hormone replacement therapy also known as oestrogen and contraceptive steroids.

Pregnancy, breast-feeding and fertility

- * 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 using this medicine - do not use Pulmicort Respules unless your doctor tells you to.
- * If you get pregnant while using Pulmicort Respules, do not stop using Pulmicort Respules but talk to your doctor immediately.

Driving and using machines

Pulmicort Respules are not likely to affect you being able to drive or use any tools or machines.

3 How to use Pulmicort Respules

- * Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- * The suspension in a Respule must be put into a nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. Instructions for using your nebuliser are given after the section 'How much to use'.
- Note:** Do not use an ultrasonic nebuliser with Pulmicort Respules.
- * Your asthma may improve within 2 days. However, it can take up to 3-6 weeks for the medicine to have its full effect. It is important to use Pulmicort Respules every day, even if you have no asthma symptoms at the time.

How much to use

Asthma

Your doctor will tell you how much to use. This will depend on how severe your asthma is. Your doctor may lower your dose as your asthma improves.

- * The recommended starting dose in adults and children over 12 years is 1 mg to 2 mg (milligrams), twice a day.
- * Children under 12 years are usually prescribed lower doses (0.5 mg to 1 mg, twice a day). The highest dose (2 mg per day) should only be used in this age group for limited periods of time in children with severe asthma.

Croup

The recommended dose for infants and children is 2 mg a day. This may be given all in one go, or 1 mg may be given followed by another 1 mg 30 minutes later.

Instructions for using Pulmicort Respules

1. Break off a Respule from the strip. Leave the rest in the foil envelope.
2. Shake the Respule gently.
3. Hold upright. Twist off the top of the Respule to open.
4. Place the open end of the Respule firmly inside the nebuliser cup. Squeeze slowly to put the liquid in the cup. The Respule is marked with a line which shows a 1 ml volume when it is held upside down. If your doctor has told you to use 1 ml (half a Respule) squeeze the Respule until the surface of the liquid reaches this line.
5. Throw the empty Respule away. Put the top back on the nebuliser cup.
6. Connect one end of the cup to the face mask or mouthpiece.
7. Connect the other end of the cup to the air pump.
8. Gently shake the cup.
9. Turn on the nebuliser and breathe in the mist calmly and deeply using the face mask or mouthpiece. If you are using a face mask, make sure the face mask fits tightly.
10. You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece.
11. How long it takes to nebulise all the medicine depends on the type of equipment you use. It will also depend on the amount of medicine to be used.
12. Rinse your mouth with water. Spit out the water. Do not swallow it. If you have used a face mask, wash your face as well.
13. After each use, you must wash the nebuliser cup and mouthpiece (or face mask) in warm soapy water and rinse well. After washing, dry these parts by connecting to the air outlet or the compressor and blow air through them.

Important information about your asthma symptoms

If you feel you are getting breathless or wheezy while using Pulmicort Respules, you should continue to use Pulmicort Respules but go to see your doctor as soon as possible, as you may need additional treatment. Contact your doctor immediately if:

- * Your breathing is getting worse or you often wake up at night with asthma.
- * Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your condition is not being properly controlled and you may need different or additional treatment immediately.

If you use more Pulmicort Respules than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. If you use more Pulmicort Respules than you should, contact your doctor or pharmacist for advice.

If you forget to use Pulmicort Respules

If you forget to take a dose, just take the next dose as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

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

If either of the following happen to you, stop using Pulmicort Respules and talk to your doctor immediately:

- * Swelling of your face, particularly around your mouth. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- * Sudden wheezing after inhaling your medicine. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- * Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using Pulmicort.
- * Mild sore throat, coughing and a hoarse voice.
- * Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking budesonide they could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties.

Uncommon (may affect up to 1 in 100 people)

- * Feeling worried, restless and nervous.
- * Depression.
- * Trembling and shaking.
- * Cataract (clouding of the lens in the eye).
- * Muscle cramps.
- * Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- * Rash, itching, contact dermatitis (a skin problem), raised itchy rash (can be red and bumpy in appearance).
- * Rash on the face after using the face mask. You can stop this from happening by washing your face after using the face mask.
- * Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Pulmicort Respules stop using Pulmicort Respules and talk to your doctor immediately.
- * Sleeping problems, aggression, over-excited or irritable. These effects are more likely to occur in children.
- * Bruising of the skin.
- * Loss of voice.
- * Hoarse voice (rare in children).
- * Behavioural changes (mainly in children).
- * Feelings of extreme restlessness accompanied by an increase in motor activity including muscle spasms, tremors and twitching, pacing, crossing and uncrossing the legs and other nervous activity.

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)

- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents (rare). Height of children should be monitored
- an effect on the adrenal gland (a small gland next to the kidney) (rare).

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Pulmicort Respules

- * Keep this medicine out of the sight and reach of children.
- * Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.
- * Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light. Units should be stored in an upright position and should be protected from freezing.
- * Once a foil envelope has been opened, the Respules inside should be used within 3 months. **Note:** It is best to mark the opening date on the foil envelope to help you remember.
- * Respules are for single use only. After use, any remaining contents should be thrown away.
- * The colour of Pulmicort Respules Nebuliser Suspension is white/off-white. Do not use this medicine if you notice the suspension is discoloured or if the container is damaged.
- * Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Pulmicort Respules 1 mg contain

- * The active substance is budesonide. Each 2 ml Respule contains 1 mg of budesonide.
- * The other ingredients are ethylenediaminetetraacetate disodium salt, sodium chloride, polysorbate 80, citric acid anhydrous, sodium citrate and water for injections.

What Pulmicort Respules 1 mg look like and the contents of the pack

White to off-white sterile suspension in plastic single dose units. The container is a low-density polyethylene single-dose plastic vial. Each plastic vial contains 2 ml of suspension. Each ml contains 0.5 mg budesonide. The package contains 5 plastic vials in an aluminium envelope. Each box contains 4 sachets.

Parallel Product Authorisation Holder:

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Tel: +35318710550 for help.