

# PULMICORT®

Budesonide

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## Consumer Medicine Information

Name of consumer

Address of consumer

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### What is in this leaflet

This leaflet answers some of the common questions people 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 will have 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.

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### What PULMICORT is for

Pulmicort is intended to be inhaled into the lungs for the treatment of asthma. This is when the lining of your lungs becomes inflamed (red and swollen), making it difficult for you to breathe. This may be due to an allergy to house dust mites, smoke, air pollution or other things that irritate your lungs.

Pulmicort acts directly on the surface of the lungs to help improve your condition and also helps stop asthma attacks occurring.

It is a "preventer" and must be taken regularly.

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

Pulmicort belongs to the family of corticosteroids, which are used to reduce inflammation in many parts of the body.

Your doctor will have explained why you are being treated with Pulmicort and told you what dose to take.

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use.

**Ask your doctor if you want more information.**

Pulmicort is not addictive.

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### Before you use PULMICORT

#### *When you must not use it*

Do not use Pulmicort if you have allergies to:

- ingredients listed at the end of this leaflet
- any other substances

If you have an allergic reaction, you may get a skin rash, hayfever, worse asthma or feel faint.

**Do not use after the use by (expiry) date printed on the pack.**

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

**Do not use Pulmicort if the packaging is torn or shows signs of tampering.**

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

**Do not give this medicine to anyone else.**

**Before you start to use it**

**You must tell your doctor or pharmacist if:**

1. **You have an allergy to any ingredient listed at the end of this leaflet.**  
Some of the symptoms of an allergic reaction may include:
  - skin rash
  - shortness of breath
  - wheezing or difficulty breathing
2. **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.

3. **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.

4. **You are pregnant or plan to become pregnant or are breast-feeding or plan to.** Your doctor can discuss with you the risks and benefits involved.

5. **You are taking oral corticosteroids.**

Your doctor can discuss with you the possible need to use additional oral steroids during periods of stress such as trauma, surgery or infections.

### **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.**

**Tell your doctor if you are taking any other medicines, including medicines used to treat fungal infections.**

These medicines may affect the way Pulmicort works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, do so before you take any Pulmicort.

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## **Using PULMICORT**

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### **How to take it**

Pulmicort comes in two different forms - Turbuhaler and a suspension (slightly cloudy liquid) 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.

### **Asthma**

#### **Adult dose:**

##### **Turbuhaler:**

The dose can range from 400 micrograms (mcg) up to 2400mcg each day.

This is taken in divided doses, either two, three or four times a day. When your asthma is under control the dose is usually lowered.

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

##### **Nebulising suspension:**

The dose can range from 1mg to 2mg each day.

This is taken in divided doses, either two, three or four times a day. When your asthma is under control the dose is usually lowered.

#### **Children's dose:**

Children are usually considered to be aged 12 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 or over before they use the Turbuhaler.

#### **Turbuhaler:**

The dose can range from 100mcg up to 800mcg each day.

This is taken in divided doses, either two, three or four times a day. When your child's asthma is under control the dose is usually lowered.

#### **Nebulising suspension:**

The dose can range from 0.5mg to 1mg each day.

This is taken in divided doses, either two, three or four times a day. When your child's asthma is under control the dose is usually lowered.

Corticosteroids taken through the nose or into the lungs (such as asthma medicines) for long periods (eg 12 months) may affect how children grow. Studies in asthmatic children taking the Pulmicort active ingredient (budesonide) through the lungs showed that, while there maybe a small decrease in growth during treatment, these patients achieved their final adult height. The amount of budesonide taken for asthma is usually more than that taken for allergies. In rare cases, some patients may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's height.

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 tell your doctor as your asthma may be getting worse.**

## **Croup**

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

### ***If you forget to take it***

**If you miss a dose take it as soon as you remember, even if your next dose is due.**

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

### **Overdose**

If you or someone else accidentally takes too much Pulmicort on one occasion, there is nothing to worry about.

However, if you take too much Pulmicort over a long time (months or years) you may start to get effects inside your body. Discuss any worries you may have about this with your doctor or pharmacist.

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## **While you are using it**

### ***Things you must do***

**Take your Pulmicort regularly for your asthma, even if you feel well.**

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

Your Pulmicort dose will be changed (up or down) by your doctor as depending on your condition.

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

If you don't you are more likely to develop thrush in your 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 taking Pulmicort for your asthma unless you have discussed it with your doctor.**

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## **Side effects**

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

Pulmicort helps most people with asthma or croup, but it may have unwanted side-effects in a few people.

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 about the possible side effects of Pulmicort.**

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

- thrush
- hoarse voice
- irritation of the tongue and mouth

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

- dry mouth
- headache
- light-headedness
- bad taste
- thirst
- diarrhoea
- nausea
- weight gain
- tiredness
- rash

- irritation of the throat
- cough

These are all mild side effects of Pulmicort.

**Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:**

- bruising
- nervousness
- restlessness
- depression
- swelling of the face, tongue or back of throat

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

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 test your adrenal glands to make sure they are working properly. Your doctor may also tell you to take additional oral corticosteroids during periods of stress such as trauma, surgery and infection. As you doctor to answer any questions you may have.

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

Some people may get other side effects while taking Pulmicort.

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## **After using it**

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### ***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 in a cool, dark place. Pulmicort Turbuhaler should be kept below 30°C, while the nebulising suspension needs to be kept between 30°C and 8°C.**

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

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.

**Do not leave it in the car on hot days.**

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## Disposal

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**Ask your pharmacist what to do with any Pulmicort you have left over if your doctor tells you to stop using it, or if the expiry date has passed.**

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## Product description

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### **Pulmicort Turbuhaler:**

Contains only budesonide as the active ingredient; either 100 micrograms, 200 mcg or 400mcg per dose. Each Turbuhaler contains 200 doses. The Turbuhaler is made of plastic parts.

### **Pulmicort Respules:**

Contain budesonide 0.5mg/2mL or 1.0mg/2mL as the active ingredient plus,

- Disodium edetate
- Sodium chloride
- Polysorbate 80 (E 433)

- Citric acid (E 330)
- Sodium citrate (E 331)
- Water for injection

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

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## Supplier

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AstraZeneca Pty Ltd  
ABN 54 009 682 311  
Alma Road  
**NORTH RYDE NSW 2113**

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### Australian Registration Number

Turbuhaler	100mcg	10063
	200mcg	10065
	400mcg	10064
Respules	0.5mg/2mL	10072
	1.0mg/2mL	10071

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