Patient Information Leaflet: PULMICORT TURBUHALER

Read this leaflet about PULMICORT TURBUHALER before you start treatment. If any of this information causes you concern or if you need more information, contact your doctor or pharmacist.

SCHEDULING STATUS: **S 3**

PROPRIETARY NAME (and dosage form):

Pulmicort® Turbuhaler® 100 µg/dose (Inhaler)

Pulmicort® Turbuhaler® 200 µg/dose (Inhaler)

Pulmicort® Turbuhaler® 400 µg/dose (Inhaler)

WHAT PULMICORT TURBUHALER CONTAINS:

PULMICORT TURBUHALER is a dry powder inhaler that contains the medicine budesonide. There are no other ingredients.

PULMICORT TURBUHALER 100 µg/dose contains 100µg of budesonide per dose/puff.

PULMICORT TURBUHALER 200 µg/dose contains 200µg of budesonide per dose/puff.

PULMICORT TURBUHALER 400 µg/dose contains 400µg of budesonide per dose/puff.

WHAT PULMICORT TURBUHALER IS USED FOR:

PULMICORT TURBUHALER is used to prevent the symptoms of asthma.

BEFORE TAKING THE MEDICINE:

When should PULMICORT TURBUHALER not be taken?

- If your doctor has told you that you have chest or lung infections or if you suffer from tuberculosis (TB).
- If you have had any unusual reactions to budesonide.
- In children under the age of 6 years.

If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

Take special care with PULMICORT TURBUHALER in the following instances:

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions, please consult your doctor, pharmacist or other health care professional for advice.

HOW TO TAKE PULMICORT TURBUHALER:

- Follow your doctor, pharmacist, or other health care professional's instructions on how to take PULMICORT TURBUHALER and ask them if you are unsure.
- Do not share medicines prescribed for you.
- Before you start using PULMICORT TURBUHALER for the first time, it is important that you read the "Instructions for use" at the end of this leaflet and follow the instructions carefully.
- Children should only use PULMICORT TURBUHALER under close supervision of an adult.

The usual dose:

The dosage prescribed to you is individualised and may differ from the information contained in this leaflet.

Starting Dose in Adults: 400 micrograms daily taken in divided doses.

The maximum daily dose is up to 1600 micrograms per day.

Starting Dose in Children (6 years and older): 200 - 400 micrograms daily in divided doses.

The maximum daily dose is up to 800 micrograms per day.

After your symptoms have improved your doctor may decide to reduce the dose.

Remember: Rinse your mouth out with water after each dose.

What do you do if you forget to take PULMICORT TURBUHALER?

If you forget to take a dose of PULMICORT TURBUHALER take the next dose as prescribed to you. Do not try to take 2 doses to make up for the missed dose.

What do you do in the event of an overdosage?

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE-EFFECTS:

The most commonly reported side effects are irritation in the throat, hoarseness and thrush in the mouth (white spots in the mouth or furry coating on the tongue with some discomfort caused). Skin reactions such as skin rash with or without redness and itching of the skin may occur.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

How do you store PULMICORT TURBUHALER?

Store at room temperature below 30°C with the cover tightened.

Store all medicines out of reach of children.

How do you dispose of PULMICORT TURBUHALER?

Take all unused or expired medicines to your pharmacist, doctor or other health care professional.

PRESENTATION:

PULMICORT TURBUHALER 100 µg/dose contains 200 doses of 100µg of budesonide.

PULMICORT TURBUHALER 200 µg/dose contains 200 doses of 200µg of budesonide.

PULMICORT TURBUHALER 400 µg/dose contains 50 or 100 doses of 400µg of budesonide.

IDENTIFICATION:

Pulmicort Turbuhaler contains white to off white round granules that break up to a fine powder when they are crushed.

The PULMICORT TURBUHALER 100 µg/dose is light brown and the bottom of the turning grip is printed with the words "Budesonide 100". On the bottom of the turning grip, a Braille code for identification of budesonide is embossed.

The PULMICORT TURBUHALER 200 µg/dose is brown and the bottom of the turning grip is embossed with the words "Budesonide 200". On the bottom of the turning grip, a Braille code for identification of budesonide is embossed.

The PULMICORT TURBUHALER 400 µg/dose is dark brown and the bottom of the turning grip is embossed with the words "Budesonide 400". On the bottom of the turning grip, a Braille code for identification of budesonide is embossed.

REGISTRATION NUMBER:

PULMICORT TURBUHALER 100 µg/dose: Y/21.5.1/171

PULMICORT TURBUHALER 200 µg/dose: Y/21.5.1/172

PULMICORT TURBUHALER 400 µg/dose: Z/21.5.1/266

NAME, BUSINESS ADDRESS AND THE TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West, Bryanston

Johannesburg, 2191

☎ (011) 797 6000

DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET:

(Date of council resolution)

AstraZeneca Logo

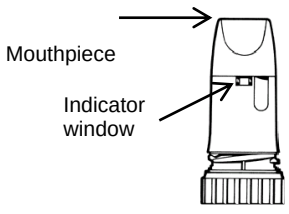
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REF: Pulmicort Turbuhaler – EPIL (MCC submission date dd/mm/yy)

EPI (MCC submission date 29-06-2015)

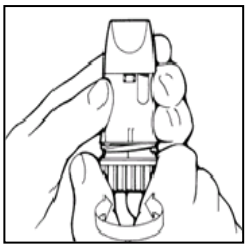
INSTRUCTIONS FOR USE/HANDLING



HOW TO USE PULMICORT TURBUHALER

Turbuhaler is a multidose inhaler from which the medicine is administered without the use of additives. When you breathe in through Turbuhaler the powder is delivered to the lungs. It is therefore important that you inhale forcefully and deeply through the mouthpiece. Turbuhaler is very easy to use. Simply follow the instructions given below.

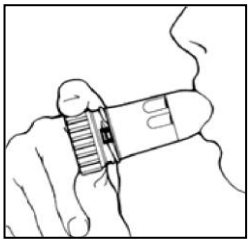
1. Unscrew and lift off the cover.



2. Hold the inhaler upright with the grip downward. Load the inhaler with a dose by turning the grip as far as it will go and then back to the original position.

3. Breathe out. Do not breathe out through the mouthpiece.

4. Place the mouthpiece gently between your teeth, close your lips and breathe in forcefully and deeply through your mouth. Do not chew or bite on the mouthpiece. Do not use Turbuhaler if it has been damaged or if the mouthpiece has become detached.



5. Before breathing out, remove the inhaler from your mouth.
   If more than one dose has been prescribed, repeat steps 2-5.

6. Replace the cover.

7. Rinse your mouth out with water after inhaling your prescribed dose.

NOTE!

Never breathe out through the mouthpiece.

Always replace the cover properly after use.

As the amount of the powder dispensed is very small, you may not be able to taste it after inhalation. However,

you can still be confident that the dose has been inhaled if you have followed the instructions.

Cleaning:

Clean the outside of the mouthpiece regularly (weekly) with a dry tissue.

Do not use water for cleaning the mouthpiece.

Dose indicator:





When a red mark is first seen in the indicator window there are approximately 20 doses left. When the red mark has reached the lower edge of the window the inhaler will no longer deliver the correct amount of medicine, and should be discarded. The sound heard as you shake the inhaler is not produced by the medication but by a drying agent.

Disposal:

Always be sure to dispose of your used Turbuhaler responsibly/in the recommended way, since some of the medicine will remain inside it.