

INFORMATION FOR THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

 PULMICORT[®] NEBUAMP[®]

(budesonide suspension for inhalation)

Before using PULMICORT NEBUAMP, read this leaflet carefully. It contains general points about PULMICORT NEBUAMP and should add to more specific advice from your doctor or pharmacist.

Please keep this leaflet to refer to until you have used up all PULMICORT NEBUAMP units in this package.

WHAT IS PULMICORT NEBUAMP USED FOR AND HOW DOES IT WORK?

PULMICORT is the brand name for an inhaled drug called budesonide. It belongs to a group of medicines called corticosteroids which are used to reduce inflammation. Asthma is caused by inflammation in the airways. PULMICORT NEBUAMP reduces and prevents this inflammation. In some cases, several weeks of regular use may be needed before the full effect is seen.

PULMICORT NEBUAMP will not relieve an asthma attack that has already started. Many inhalers contain bronchodilators to provide rapid relief. If your doctor prescribed one of these, you should follow his or her directions when you have an acute attack of asthma.

WHAT IS IN PULMICORT NEBUAMP?

PULMICORT NEBUAMP contains budesonide as the active ingredient and comes in concentrations of either 0.125 mg/mL, 0.25 mg/mL or 0.5 mg/mL. Each unit contains 2 mL. This means that one unit of the 0.125 mg/mL strength contains 0.25 mg of active drug. One unit of the 0.25 mg/mL strength contains 0.5 mg of active drug. One unit of the 0.5 mg/mL strength contains 1.0 mg of active drug.

Most medicines contain more ingredients than just the active drug. Check with your doctor if you think you might be allergic to any of these items (listed in alphabetical order): budesonide, citric acid, disodium edetate, polysorbate 80, sodium chloride, sodium citrate.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING PULMICORT NEBUAMP?

Tell your doctor:

- about **all** health problems you have now or have had in the past, especially if you have had lung tuberculosis or any other recent infection;
- about other medicines you take, including ones you can buy without a prescription;
- if you take, or have taken steroid medicines within the past several months;
- if you are pregnant, plan to become pregnant or are breast feeding;
- if you are allergic to "non-medicinal" substances like food products, preservatives, or dyes, which may be present in PULMICORT NEBUAMP (See 'What Is In PULMICORT NEBUAMP?')
- if you have ever had a bad, unusual or allergic reaction to any medicine containing "budesonide".
- if you take medications against fungal infections or Ritonavir (medication used to treat HIV infection or AIDS). These medications may interact with PULMICORT NEBUAMP.

WHILE TAKING PULMICORT NEBUAMP

If you develop an infection or a respiratory infection, contact your doctor to see if you can continue taking PULMICORT NEBUAMP.

DO NOT TAKE PULMICORT NEBUAMP IF:

You are allergic to budesonide or to the other ingredients in PULMICORT NEBUAMP (See 'What Is In PULMICORT NEBUAMP?')

HOW DO I TAKE PULMICORT NEBUAMP PROPERLY?

PULMICORT NEBUAMP is for use in a nebulizer or respirator. **Do not use in an ultrasonic nebulizer.** Be sure you know how to use your nebulizer or respirator before you start this drug.

Nebulization should take place using a gas flow (oxygen or compressed air) of 6 to 10 L/minute. A suitable volume fill for most nebulizers is 2 to 4 mL.

It is important that you use PULMICORT NEBUAMP daily as recommended by your doctor, even when you feel well. Do not take more doses than prescribed by your doctor. Using more can increase the chance of unwanted effects. **Contact your doctor right away if your asthma seems worse.**

Before use, check to make sure the strength on the label matches the strength your doctor prescribed.

Follow these directions for each dose of PULMICORT NEBUAMP:

1. Remove 1 PULMICORT NEBUAMP from a sheet of 5 units. Return the other units to the envelope.
2. Gently shake the unit.
3. Open by holding the unit upright and twisting off the top “wing”.
4. Slowly squeeze the contents of the unit into the nebulizer cup. If you only need to use half the contents of a unit, add sterile saline to the cup as instructed by your doctor or pharmacist. Before you use the rest of the unit for the next dose, swirl it gently.



5. Connect one end of the cup to the face mask or mouthpiece, and the other end to the air pump.
6. Just before you start treatment, gently shake the contents of the cup again. Then start the treatment.
7. Breathe calmly and evenly until no more mist comes out (about 10-15 minutes).
8. Rinse your mouth and spit out as soon as you are done.
9. If you use a face mask, wash your face after treatment.

Cleaning: When you have finished, you have to clean the nebulizer. Wash the cup and the mouth piece or mask in warm water, using a mild detergent. Rinse well. Dry by connecting the nebulizer cup to the compressor or to the air inlet. See the manufacturer's instructions for complete details.

HOW MUCH PULMICORT NEBUAMP SHOULD I TAKE?

The dosage of PULMICORT NEBUAMP is individual.

Follow your doctor's directions carefully. They may differ from the information in this leaflet.

Suggested doses are:

Initially

Children (3 months to 12 years): 0.25 to 0.5 mg twice daily.

Adults: Usually 1 to 2 mg twice daily.

Maintenance

After the desired effect has been obtained, your doctor can reduce your dose to the smallest amount necessary to control your asthma symptoms.

Dosage Table

Dose in mg	Volume of PULMICORT NEBUAMP		
	0.125 mg/mL	0.25 mg/mL	0.5 mg/mL
0.125 mg	1 mL* (½ unit)	-	-
0.25 mg	2 mL (1 unit)	1 mL* (½ unit)	-
0.5 mg	4 mL (2 units)	2 mL (1 unit)	-
0.75 mg	-	3 mL (1½ units)	-
1 mg	-	-	2 mL (1 unit)
1.5 mg	-	-	3 mL (1½ units)
2 mg	-	-	4 mL (2 units)

* This should be mixed with 0.9% saline to a volume of 2 mL.

WHAT DO I DO IF I MISS A DOSE?

If you miss a dose of PULMICORT NEBUAMP, take it as soon as possible. Then go back to your regular schedule. If it is almost time for your next dose, skip the missed dose and take the next dose on time.

Never take a double dose of PULMICORT NEBUAMP to make up for ones you missed.

If you are still unsure, check with your doctor or pharmacist to see what you should do.

Do not stop treatment with PULMICORT NEBUAMP abruptly. Treatment should be tapered off gradually.

WHAT SHOULD I DO IN CASE OF OVERDOSE?

Telephone your doctor or go to your nearest hospital right away if you think that you or anyone else may have taken too much PULMICORT NEBUAMP.

ARE THERE ANY SIDE EFFECTS?

Like any medication, PULMICORT NEBUAMP may cause side effects in some people.

The most common side effects are cough, throat irritation, and hoarseness. Other side effects that may occur are bad taste, headache, nausea, dryness of the throat, tiredness, thirst, and diarrhea. Skin irritation on the face has been reported in a few cases when a nebulizer with face mask has been used. This can be prevented by washing the face after use of the face mask, or applying a thin layer of vaseline on the face, before using the mask.

In rare cases skin reactions like rash, nervousness, restlessness, depression, behavioural disturbances and a feeling of tightness of the airways may occur. Severe allergic reactions may also occur in rare cases following the use of PULMICORT NEBUAMP.

If you take PULMICORT for a long period and at higher doses you may develop symptoms of adrenal insufficiency. If you develop symptoms such as tiredness, headache, nausea, vomiting, pain in muscles and joints, please contact your doctor.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. If any side effects bother you, please contact your doctor.

Do not stop taking PULMICORT NEBUAMP on your own. Your doctor may want to slowly reduce your dose, especially if you have been using PULMICORT NEBUAMP for a long time. Although rare, symptoms of steroid withdrawal (i.e. fatigue, muscle or joint aches) may occur if PULMICORT NEBUAMP is stopped too quickly.

If you have to go into hospital for an operation, take your PULMICORT NEBUAMP with you and tell your doctor what medicine(s) you are taking.

WHERE SHOULD I KEEP PULMICORT NEBUAMP?

Remember to **keep PULMICORT NEBUAMP well out of the reach of children** when you are not using it.

Always keep unopened units in the foil envelope so they are well protected from light.

Do not use PULMICORT NEBUAMP after the expiry date marked on the foil envelope and outer carton.

- Record the date when the foil envelope is first opened. Do not use units from a foil envelope that has been opened for 3 months or more.
- If you are only required to use half the contents of a unit, the remainder must be used within 12 hours after the unit has been opened. If you do not use a full unit for each dose, protect the rest from light.

Store PULMICORT NEBUAMP at 5-30°C, protected from light.

Important Note

This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using PULMICORT NEBUAMP.

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. Please refer to the Consumer Information Leaflet located at www.astrazeneca.ca, to see if more up-to-date information has been posted.

Consumer Inquiries: 1 (800) 668-6000

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