

Patient Information and Instructions for Use

PULMICORT FLEXHALER™ 180 mcg

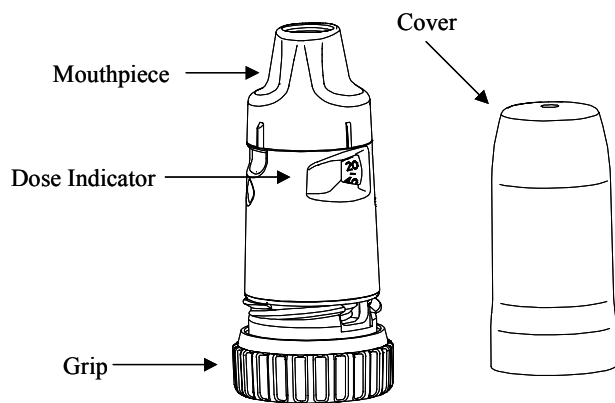
(budesonide inhalation powder, 180 mcg)

PULMICORT FLEXHALER™ 90 mcg

(budesonide inhalation powder, 90 mcg)

(bēw DEH so nide)

**For Oral Inhalation Only.
Rx Only**



Please read this leaflet carefully before you start to take your medicine. It provides a summary of information on your medicine. Following these instructions helps to ensure that you are inhaling the medication correctly.

FOR FURTHER INFORMATION ASK YOUR DOCTOR, HEALTHCARE PROFESSIONAL, OR PHARMACIST.

WHAT YOU SHOULD KNOW ABOUT PULMICORT FLEXHALER

Your doctor or healthcare professional has prescribed PULMICORT FLEXHALER 180 mcg or PULMICORT FLEXHALER 90 mcg. Both contain a medication called budesonide, which is a synthetic corticosteroid. Corticosteroids are natural substances found in the body that help fight inflammation. They are used to treat asthma because they reduce the swelling and irritation in the walls of the small air passages in the lungs and ease breathing problems. When inhaled regularly, corticosteroids also help to prevent attacks of asthma.

PULMICORT FLEXHALER treats the inflammation—the “quiet part” of asthma that you cannot hear, see, or feel. When inflammation is left untreated, asthma symptoms and attacks can increase. PULMICORT FLEXHALER works to prevent and reduce your asthma symptoms and attacks.

IMPORTANT POINTS TO REMEMBER ABOUT PULMICORT FLEXHALER

- ❶ MAKE SURE that this medicine is suitable for you (see “BEFORE USING YOUR PULMICORT FLEXHALER”).
- ❷ It is important that you inhale each dose as your doctor or healthcare professional has advised.
- ❸ **DO NOT STOP TREATMENT OR REDUCE YOUR DOSE EVEN IF YOU FEEL BETTER**, unless told to do so by your doctor or healthcare professional. Use PULMICORT FLEXHALER as directed by your doctor or healthcare professional.
- ❹ **DO NOT** inhale more doses or use your PULMICORT FLEXHALER more often than instructed by your doctor or healthcare professional.
- ❺ You may not sense the presence of any medication entering your lungs when inhaling from PULMICORT FLEXHALER. This lack of sensation does not mean that you did not get the medication. **You should not repeat your inhalations even if you did not feel the medication when inhaling.**
- ❻ This medicine is **NOT** intended to provide rapid relief of your breathing difficulties during an asthma attack. It must be taken at regular intervals as recommended by your doctor or healthcare professional, and not as an emergency measure.
- ❼ Your doctor or healthcare professional may prescribe additional medication (such as bronchodilators) for emergency relief if an acute asthma attack occurs. Please contact your doctor or healthcare professional if:
 - an asthma attack does not respond to the additional medication,
 - you require more of the additional medication than usual.
- ❽ If you also use another medicine by inhalation, you should consult your doctor or healthcare professional for instructions on when to use it in relation to using your PULMICORT FLEXHALER.

WHAT IS PULMICORT FLEXHALER?

PULMICORT FLEXHALER is an inhaled corticosteroid approved for adults and children 6 years of age and older. It is a long-term controller (preventive or maintenance) asthma medicine. Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms.

WHAT IS ASTHMA?

Asthma is a condition that interferes with your breathing by preventing air from flowing freely into and out of the lungs. In patients with asthma, the airways become inflamed (swollen and irritated) and the muscles around the airways tighten.

HOW DOES PULMICORT FLEXHALER WORK?

PULMICORT FLEXHALER is a dry powder inhaler that delivers medication through inhalation as you deeply inhale. The inhaler delivers your medicine as a very fine powder. PULMICORT FLEXHALER helps reduce inflammation and helps keep the airways open to reduce asthma symptoms.

BEFORE USING YOUR PULMICORT FLEXHALER

TELL YOUR DOCTOR OR HEALTHCARE PROFESSIONAL BEFORE STARTING TO TAKE THIS MEDICINE IF YOU:

- are pregnant (or intending to become pregnant),
 - are breast-feeding a baby,
 - are allergic to any ingredient (see **WHAT ARE THE INGREDIENTS IN PULMICORT FLEXHALER?**).
- PULMICORT FLEXHALER** contains small amounts of lactose (milk sugar), which contains trace levels of milk proteins. It is possible that cough, wheezing, or bronchospasm may occur in patients who have a severe milk protein allergy. This small amount of lactose in PULMICORT FLEXHALER does not typically cause problems in lactose intolerant people.
- have any infections,
 - have or had tuberculosis,
 - have osteoporosis,
 - have recently been around anyone with chicken pox or measles,
 - are planning to have surgery,
 - have been taking an oral corticosteroid medicine like prednisone. You may have to follow specific instructions to avoid health risks associated with stopping the use of these types of medicines.

In some circumstances, this medicine may not be suitable and your doctor or healthcare professional may wish to prescribe a different medicine. Make sure that your doctor or healthcare professional knows what other medicines you are taking including prescription and non-prescription medicines, as well as any vitamins or dietary and herbal supplements.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF PULMICORT FLEXHALER?

As with all inhaled corticosteroids, you should be aware of the following side effects:

- **Increased wheezing right after taking PULMICORT FLEXHALER. Always have a short-acting bronchodilator medicine with you to treat sudden wheezing.** Short-acting bronchodilator medicines help to relax the muscles around the airways in your lungs. Wheezing happens when the muscles around the airways tighten. This makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right away.
- **Immune system effects and a higher chance of infections.**
- **Eye problems including glaucoma and cataracts.** Eye examinations should be considered while using PULMICORT FLEXHALER.
- A child's growth should be checked regularly while taking PULMICORT FLEXHALER because of the potential for slowed growth.

Based on clinical trials, the most common side effects reported by patients using PULMICORT FLEXHALER are:

- Sore nose and throat
- Stuffy nose
- Hay fever

- Viral infections in the upper respiratory tract

These are not all of the possible side effects of PULMICORT FLEXHALER. For more information, ask your doctor, healthcare professional, or pharmacist.

USING YOUR PULMICORT FLEXHALER

- Follow the instructions shown in the section “HOW TO USE YOUR PULMICORT FLEXHALER”. If you have any questions, talk with your doctor, healthcare professional or pharmacist.
- It is important that you inhale each dose as directed by your doctor or healthcare professional. The pharmacy label will usually tell you what dose to take and how often. If it doesn't, or if you are not sure, ask your doctor, healthcare professional, or pharmacist.

DOSAGE

- You can determine which strength of PULMICORT FLEXHALER you have (either 180 mcg or 90 mcg) by looking at the label on the cover or by what is printed on the inhaler itself.
- Use as directed by your doctor or healthcare professional.
- It is **VERY IMPORTANT** that you follow your doctor or healthcare professional's instructions as to how many inhalations to take and how often to use your PULMICORT FLEXHALER.
- **DO NOT** inhale more doses or use your PULMICORT FLEXHALER more often than your doctor or healthcare professional advises.
- You may not sense the presence of any medication entering your lungs when inhaling from PULMICORT FLEXHALER. This lack of sensation does not mean that you did not get the medication. You should not repeat your inhalations even if you did not feel the medication when inhaling.
- It may take 1 to 2 weeks or longer before you feel maximum improvement, so **IT IS VERY IMPORTANT THAT YOU USE PULMICORT FLEXHALER REGULARLY. DO NOT STOP TREATMENT OR REDUCE YOUR DOSE EVEN IF YOU ARE FEELING BETTER**, unless told to do so by your doctor or healthcare professional.
- If you miss a dose, just take your regularly scheduled next dose when it is due. **DO NOT DOUBLE** the dose.

WHAT ARE THE INGREDIENTS IN PULMICORT FLEXHALER?

PULMICORT FLEXHALER contains budesonide as the active ingredient and lactose (which contains trace levels of milk proteins), an inactive ingredient (see BEFORE USING YOUR PULMICORT FLEXHALER).

HOW TO USE YOUR PULMICORT FLEXHALER

Read the complete instructions carefully and use only as directed.

PRIMING INSTRUCTIONS:

Before you use a new PULMICORT FLEXHALER for the first time, you must prime it.

To prime your PULMICORT FLEXHALER, follow the steps below:

1. Hold the unit so that the white cover points upward, grasp the inhaler by the brown grip in one hand and with the other hand, turn the white cover and lift it off.
2. Hold PULMICORT FLEXHALER by the brown grip, in the upright position (with mouthpiece up) in one hand. Using the thumb and index finger of your other hand, grasp the inhaler in the middle. **DO NOT HOLD THE INHALER AT THE TOP OF THE MOUTHPIECE.**
3. Twist the brown grip as far as it will go in one direction and then fully back again in the other direction until it stops (it does not matter which way you turn it first). You will hear a click during one of the twisting movements.
4. Repeat Step 3. Your PULMICORT FLEXHALER is now primed.

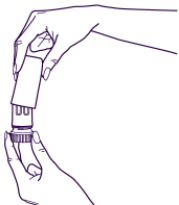
YOU DO NOT HAVE TO PRIME IT ANY OTHER TIME AFTER THIS, EVEN IF YOU PUT IT ASIDE FOR A PROLONGED PERIOD OF TIME.

Now you are ready to load your first dose (see instructions for “LOADING A DOSE”).

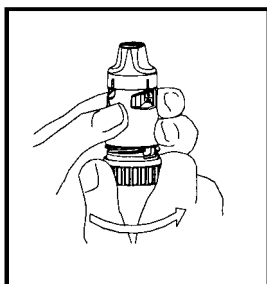
TAKING A DOSE:

① LOADING A DOSE

- Twist the cover and lift it off.

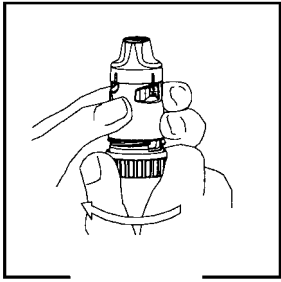


- In order to load the correct dose, **PULMICORT FLEXHALER must be held in the upright position (mouthpiece up) whenever a dose of medication is being loaded.**
- Do not hold the mouthpiece when you load the inhaler.
- Twist the brown grip fully in one direction as far as it will go. Twist it fully back again in the other direction as far as it will go (it does not matter which way you turn it first).



Twist

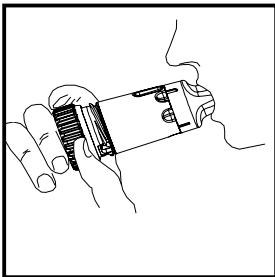
- You will hear a click during one of the twisting movements.



Click

- PULMICORT FLEXHALER is designed to deliver only one dose at a time, no matter how often you click the brown grip, although the dose indicator will continue to advance. If you accidentally blow into your inhaler after loading a dose, simply follow the instructions for loading a new dose.

② INHALING THE DOSE



Inhale

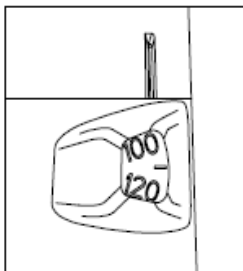
- Turn your head away from the inhaler and breathe out. **Do not shake the inhaler after loading it.**
- Place the mouthpiece in your mouth, close your lips around the mouthpiece, and inhale deeply and forcefully through the inhaler.
- You may not sense the presence of any medication entering your lungs when inhaling from PULMICORT FLEXHALER. This lack of sensation does not mean that you did not get the medication. You should not repeat your inhalations even if you did not feel the medication when inhaling.
- Do not chew or bite on the mouthpiece.
- Remove the inhaler from your mouth and exhale. **Do not blow or exhale into the mouthpiece.**
- If more than one dose is required, just repeat the steps above.
- **When you are finished, place the cover back on the inhaler and twist shut. Rinse your mouth with water after each dose to reduce the risk of developing thrush. Do not swallow.**
- Do not use PULMICORT FLEXHALER if it has been damaged or if the mouthpiece has become detached.

READING THE DOSE INDICATOR WINDOW

- The label on the box or cover will tell you how many doses are in your PULMICORT FLEXHALER.
- Your PULMICORT FLEXHALER has a convenient dose indicator window just below the mouthpiece. The dose indicator tells approximately how many doses remain in the inhaler. Look at the middle of the window to find out how many doses are left in your inhaler.
- The dose indicator is connected to the turning grip and moves (counts down) every time a dose is loaded. **It is unlikely that you will see the dose indicator move with each individual dose.** Advancement of the indicator can be seen after intervals of 5 or so doses.
- The dose indicator starts with either the number 60 or 120 when full, depending upon the strength of the product. The indicator is marked in intervals of 10 doses, alternating numbers and dashes, down to “0”.

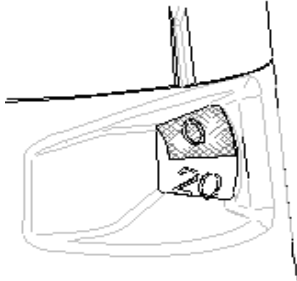
60 Dose Inhaler	120 Dose Inhaler	
20	80	Dose indicator starts at 60 or 120 depending on strength (90 mcg or 180 mcg) of the product and counts down to 0.
–	–	
40	100	
–	–	
60	120	

- The dose indicator will always tell approximately how many doses are left in the PULMICORT FLEXHALER. The dose indicator counts down each time a dose is loaded, not when a dose is inhaled.



- **If the instructions for loading the dose are completed more than once prior to inhaling the dose, only one dose will be received.** However, the dose indicator will advance slightly but it is unlikely that you will see the dose indicator move with each individual dose.

- **Your inhaler is empty when the number 0 on the red background has reached the middle of the window. At this time, your inhaler should be discarded, as it may no longer deliver the correct amount of medication, even though it may not feel completely empty and may continue to operate.**



(You may still hear a sound if you shake it—this sound is not the medicine. This sound is produced by the drying agent inside.)

- The grip will still twist and “click” even when your inhaler is empty.
- Remember, you will get a new inhaler each time you refill your prescription.
- **Do not immerse it in water to find out if it is empty. Simply check your dose indicator window.**

CLEANING YOUR PULMICORT FLEXHALER

- **Keep your PULMICORT FLEXHALER clean and dry at all times. Do not immerse it in water.**
- Wipe the outside of the mouthpiece once a week with a dry tissue.
- **Do not use water or liquids when cleaning the mouthpiece.**
- Do not try to remove the mouthpiece or twist it unnecessarily.

STORING YOUR PULMICORT FLEXHALER

- After each use, place the white cover back on and twist it tightly into place.
- Store PULMICORT FLEXHALER in a dry place at controlled room temperature, 68-77°F (20-25°C) with the cover tightly in place.
- Keep your PULMICORT FLEXHALER in a secure place out of the **reach of young children.**
- **DO NOT** use after the date shown on the body of your inhaler.

FURTHER INFORMATION ABOUT PULMICORT FLEXHALER

- PULMICORT FLEXHALER delivers your medicine as a very fine powder. Because of this, you may not sense the presence of any medication entering your lungs when inhaling from PULMICORT FLEXHALER. This lack of sensation does not mean that you did not get the medication. You should not repeat your inhalations even if you did not feel the medication when inhaling.
- PULMICORT FLEXHALER should not be used with a spacer.

This leaflet does not contain the complete information about your medicine. If you have any questions, or are not sure about something, then you should ask your doctor, healthcare professional, or pharmacist.

You may want to read this leaflet again. Please DO NOT THROW IT AWAY until you have finished your medicine.

REMEMBER: This medicine has been prescribed for you by your doctor or healthcare professional. DO NOT give this medicine to anyone else.

USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR DOCTOR OR HEALTHCARE PROFESSIONAL.

For additional information about PULMICORT FLEXHALER, please visit our website: pulmicortflexhaler.com or call the AstraZeneca Information Center at: 1-800-236-9933, Monday through Friday, 8 am – 7 pm ET, excluding holidays

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Manufactured for: AstraZeneca LP, Wilmington DE 19850

By: AstraZeneca AB, Södertälje, Sweden

Product of Sweden

33023-XX

Rev. XX/08