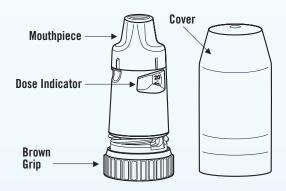
How to Get Started Using Your PULMICORT FLEXHALER® (budesonide inhalation powder, 90 mcg & 180 mcg)

Please read these instructions carefully before you start to take your medicine, and use only as directed by a health care professional.

Priming Your PULMICORT FLEXHALER

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

Figure 1- Parts of your PULMICORT FLEXHALER



To prime your PULMICORT FLEXHALER follow the steps below:

- 1. Hold the inhaler by the brown grip so that the white cover points upward (upright position). With the other hand, turn the white cover and lift off (see Figure 2).
- 2. Continue to hold your PULMICORT FLEXHALER upright as shown in Figure 1. Use your other hand to hold 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 (see Figure 3 and 4).
- **4.** Repeat Step 3. Your PULMICORT FLEXHALER is now primed. You are ready to load your first dose.

You do not have to prime your PULMICORT FLEXHALER again after this even if you do not use it for a period of time.









Figure 2 - Load

Figure 3 - Twist

Figure 4 - Click

Figure 5 - Inhale

Loading a Dose

- 1. Hold your PULMICORT FLEXHALER upright as described above. With your other hand, twist the white cover and lift it off (see Figure 2).
- Continue to hold your PULMICORT FLEXHALER upright to be sure that the right dose of medicine is loaded.
- Use your other hand to hold the inhaler in the middle. Do not hold the mouthpiece when you load the inhaler.
- **4.** 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) [see Figure 3].
 - You will hear a "click" during one of the twisting movements (see Figure 4)
 - PULMICORT FLEXHALER will only give one dose at a time, no matter how often you click the
 brown grip, but the dose indicator will continue to move (advance). This means that
 if you continue to move the brown grip, it is possible for the indicator to show fewer doses
 or zero doses even if more doses are left in the inhaler
 - Do not shake the inhaler after loading it

Inhaling a Dose

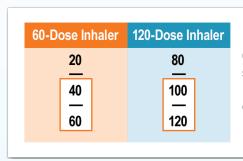
- **1.** Turn your head away from the inhaler and breathe out (exhale). If you accidentally blow into your inhaler after loading a dose, follow the instructions for loading a new dose.
- Place the mouthpiece in your mouth and close your lips around the mouthpiece.Breathe in (inhale) deeply and forcefully through the inhaler (see Figure 5).
- 3. 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.
- 4. Do not chew or bite on the mouthpiece.
- 5. Remove the inhaler from your mouth and exhale. Do not blow or exhale into the mouthpiece.
- **6.** If more than one dose is prescribed repeat the steps above.
- **7.** When you are finished taking your dose, place the white cover back on the inhaler and twist shut.
- 8. Rinse your mouth with water after each dose to decrease your risk of getting thrush. Do not swallow the water.



(budesonide inhalation powder, 90 mcg & 180 mcg)

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 dose indicator window just below the mouthpiece. The dose indicator tells you about how many doses are left in the inhaler. Look at the middle of the window to find out about how many doses are left in your inhaler (see Figure 6)
- The dose indicator is connected to the turning grip and moves (counts down) every time a dose is loaded. It is not likely that you will see the dose indicator move with each dose. You can usually see the indicator move each time you use about 5 doses
- The dose indicator starts with either the number 60 or 120 when full, depending upon the strength of the inhaler. The indicator is marked in intervals of 10 doses. Markings are either with numbers or dashes (alternating), counting down to "0"



Dose indicator starts at 60 or 120 depending on strength (90 mcg or 180 mcg) of the inhaler and counts down to 0.

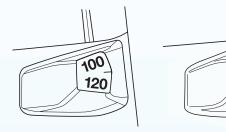


Figure 6 - Dose Indicator

Figure 7 - **Empty**

- The dose indicator will tell you about how many doses are left in your PULMICORT FLEXHALER
- If you complete the instructions for loading the dose more than one time before you inhale the dose, you will only receive one dose. The dose indicator will move a
 small amount but it is not likely that you will see the dose indicator move with each dose
- Your inhaler is empty when the number 0 on the red background reaches the middle of the dose indicator window. Throw away this inhaler. The inhaler may not give you the right amount of medicine, even though it may not feel completely empty and may seem like it continues to work (see Figure 7)
- Do not put your PULMICORT FLEXHALER in water (do not immerse it) to find out if it is empty. Check the dose indicator window to see how many doses are left
- Refill your PULMICORT FLEXHALER prescription before your medicine runs out. You will get a new inhaler each time you refill your prescription

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 one time each 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

Do not use your PULMICORT FLEXHALER if it has been damaged or if the mouthpiece has become detached. Talk to your doctor or pharmacist if you have any problems with your PULMICORT FLEXHALER.

IMPORTANT INFORMATION ABOUT PULMICORT FLEXHALER

Important Safety Information

PULMICORT FLEXHALER is not a bronchodilator and should NOT be used to treat an acute asthma attack. If you are switching to PULMICORT FLEXHALER from an oral corticosteroid, follow your doctor's instructions to avoid serious health risks when you stop using oral corticosteroids.

Avoid exposure to infections such as chicken pox and measles. Tell your doctor immediately if exposed. Inhaled corticosteroids may cause a reduction in growth rate. The long-term effect on final adult height is unknown.

Rare instances of glaucoma, increased intraocular pressure, cataracts have been reported following the inhaled administration of corticosteroids.

Please see last page for continued Important Safety Information on PULMICORT FLEXHALER



Important Safety Information (continued)

PULMICORT FLEXHALER contains small amounts of lactose, which contains trace levels of milk proteins. In patients who have severe milk protein allergy (not those who are lactose intolerant) cough, wheezing, or bronchospasm may occur.

Be sure to tell your healthcare provider about all your health conditions, and all medicines you may be taking.

As with other inhaled asthma medications, bronchospasm, with an immediate increase in wheezing, may occur after dosing. If bronchospasm occurs following dosing with PULMICORT FLEXHALER, it should be treated immediately with a fast-acting inhaled bronchodilator. Treatment with PULMICORT FLEXHALER should be discontinued and alternate therapy instituted.

The most commonly reported side effects in clinical trials include inflammation of the nose and throat, nasal congestion, sore throat, nasal allergies, viral upper respiratory tract infection, and thrush in the mouth and throat.

Approved Use

PULMICORT FLEXHALER® (budesonide inhalation powder, 90 mcg & 180 mcg), an inhaled corticosteroid, is used for the maintenance treatment of asthma in adults and children 6 years or older.

Please see full Prescribing Information for PULMICORT FLEXHALER.







