

## Pulmicort®-F

Formoterol Fumarate Dihydrate  
and Budesonide

**Description:** Formoterol is a very potent, long-acting, beta2 adrenoceptor-agonist with a high intrinsic activity and a rapid onset of action. **Pulmicort®-F** is a combination of Formoterol Fumarate Dihydrate and Budesonide. Budesonide is a potent glucocorticoid that binds with high affinity to the glucocorticoid receptor. It has a high ratio of topical to systemic activity.

**Indications:** **Pulmicort®-F** is indicated in the regular treatment of asthma, where the use of a combination (long-acting, beta2-agonist and inhaled corticosteroid) has been found to be appropriate. It is also indicated in the symptomatic treatment of severe chronic obstructive pulmonary disease (COPD), with a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.

**Composition:** **Pulmicort®-F 160/4.5 mcg HFA Inhaler:** Each actuation delivers Budesonide BP 160 mcg & Formoterol Fumarate Dihydrate BP 4.5 mcg. It does not contain CFC as propellant.

### Dosage & administration: For asthma:

As both maintenance and reliever therapy:

Adults and adolescents (12 years and older): The recommended maintenance dose is 1 puff twice daily or 2 puffs once daily. For some patients a maintenance dose of 2 puffs twice daily may be appropriate (for 160/4.5 mcg/inhalation only). Patients should take 1 additional puff as needed in response to symptoms. If symptoms persist after a few minutes, the additional puff should be taken. Not more than 6 puffs should be taken on any single occasion.

Children (4 years and older): The usual maintenance dose is 1-2 puffs once or twice daily. Patients should take 1 additional puff as needed in response to symptoms. If symptoms persist after a few minutes, the additional puff should be taken. Not more than 4 puffs should be taken on any single occasion.

A reassessment of asthma therapy should be considered in patients using an increasing number of this inhalations for symptom relief without achieving improved asthma control within 2 weeks. A total daily dose of more than 8 inhalations for adults and adolescents and 4 inhalations for children is not normally needed, however a total daily dose of up to 12 puffs for adults and adolescents and 8 inhalations for children could be used temporarily.

Only as maintenance therapy:

Adults (18 years and older): (80/4.5 and 160/4.5 mcg/inhalation): Usual dose is 1- 2 puffs twice daily. Maximum dose is 4 puffs twice daily.

Adolescents (12-17 years): (80/4.5 and 160/4.5 mcg/inhalation): 1-2 puffs twice daily.

Children (4-11 years): (80/4.5 mcg/inhalation): 1-2

puffs once or twice daily.

For COPD:

The recommended dose is 2 puffs twice daily of inhalation (160/4.5).

**Contraindications:** **Pulmicort®-F** is contraindicated in patients with a history of hypersensitivity to any of the components of the drug product.

**Side effects:** Since **Pulmicort®-F** contains both Budesonide and Formoterol, the same pattern of undesirable effects as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds.

**Formoterol:** Most common adverse events with Formoterol are tremor, palpitations, headache etc. some uncommon and rare adverse events that occurred in the groups receiving Formoterol are cardiac arrhythmias, muscle cramps, and hypersensitivity reactions such as rash, oedema and angio-oedema etc.

**Budesonide:** The incidence of common adverse events with Budesonide are oropharyngeal candidiasis, hoarseness or throat irritation, dysphonia, back pain, nausea, sinusitis, adrenal suppression, etc.

Pharmacodynamics Properties

**Mechanism of action:** **Pulmicort®-F** contains both Budesonide and Formoterol; therefore, the mechanisms of action described below for the individual components apply to **Pulmicort®-F**. These drugs represent two classes of medications (asynthetic corticosteroid and a long-acting, selective beta2-adrenoceptor agonist) that have different effects on the clinical, physiological, and inflammatory indices of Chronic Obstructive Pulmonary Disease (COPD) and asthma.

**Budesonide:** Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity. Corticosteroids have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and nonallergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in COPD and asthma.

**Formoterol Fumarate:** Formoterol Fumarate is a long-acting, selective beta2- adrenergic agonist with a rapid onset of action. Inhaled Formoterol Fumarate acts locally in the lungs as a bronchodilator.

**Warnings and Precautions:** It is recommended that the dose is tapered when the treatment is discontinued and should not be stopped abruptly. If patients find the treatment ineffective, or exceed the highest recommended dose of **Pulmicort®-F**, medical attention must be sought. Sudden and progressive deterioration in control of asthma is potentially life

threatening and the patient should undergo urgent medical assessment. In this situation consideration should be given to the need for increased therapy with corticosteroids e.g. a course of oral corticosteroids, or antibiotic treatment if an infection is present. Patients should be advised to have their rescue inhaler available at all times, either **Pulmicort®-F** (for patients using **Pulmicort®-F** as maintenance and reliever therapy) or a separate rapid-acting bronchodilator (for patients using **Pulmicort®-F** as maintenance therapy only). Patients should be reminded to take their **Pulmicort®-F** maintenance dose as prescribed, even when asymptomatic. The prophylactic use of **Pulmicort®-F**, e.g. before exercise, has not been studied. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of **Pulmicort®-F**.

Regular review of patients as treatment is stepped down is important. The lowest effective dose of **Pulmicort®-F** should be used.

**Precaution for Paediatric use:** It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of inhaled corticosteroid. The benefits of the corticosteroid therapy and the possible risks of growth suppression must be carefully weighed. In addition consideration should be given to referring the patient to a paediatric respiratory specialist. Limited data from long-term studies suggest that most children and adolescents treated with inhaled budesonide will ultimately achieve their adult target height.

**Drug interactions:** The metabolic conversion of Budesonide is impeded by substances metabolized by CYP P450 3A4 (e.g. itraconazole, ritonavir). The concomitant administration of these potent inhibitors should be avoided unless the benefit outweighs the increased risk of systemic side-effects. In patients using potent CYP3A4 inhibitors, **Pulmicort®-F** maintenance and reliever therapy is not recommended.

**Use During Pregnancy and Lactation:** There are no adequate data from use of Formoterol and Budesonide in pregnant women. Administration of **Pulmicort®-F** in pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. It is not known whether Formoterol passes into human breast milk.

**Storage:** Keep out of reach of children. Store in a dry place, below 30°C temperature and protected from light.

**Packaging:** **Pulmicort®-F 160/4.5 HFA Inhaler:** Each canister contains 120 metered dose inhalations. **Pulmicort®-F 160/4.5 60'P HFA Inhaler:** Each canister contains 60 metered dose inhalations.

### Important Information for the Patients

#### Prime your Pulmicort®-F Inhaler

**Pulmicort®-F** inhaler should be primed before using it for the first time. You should also prime your inhaler when the inhaler has not been used for more than 14 days or when the inhaler has been dropped.

প্রথম বার **পালমিকর্ট®-এফ** ইনহেলার ব্যবহারের সময় আপনাকে এটিকে প্রাইম করে নিতে হবে। এমনকি ১৪ দিন বা তার বেশি দিন ব্যবহার না করলেও এটিকে প্রাইম করে নেওয়া প্রয়োজন।

What do we mean by 'Priming' of the inhaler?

ইনহেলার প্রাইম করা বলতে কি বুঝায়?

When using your new inhaler for the first time or if it has not been used for 14 days or more, you should prime your inhaler before use. This is known as priming.

ইনহেলার প্রথম ব্যবহার বা ১৪ দিন বিরতিতে ব্যবহার করার সময় এটির পরীক্ষামূলক ব্যবহার প্রয়োজন। একেই প্রাইম করা বলে।

How to prime the inhaler?

কিভাবে প্রাইম করতে হয়?

To prime, simply shake the inhaler well and then spray 4 times into the air away from your face, shake well before each spray.

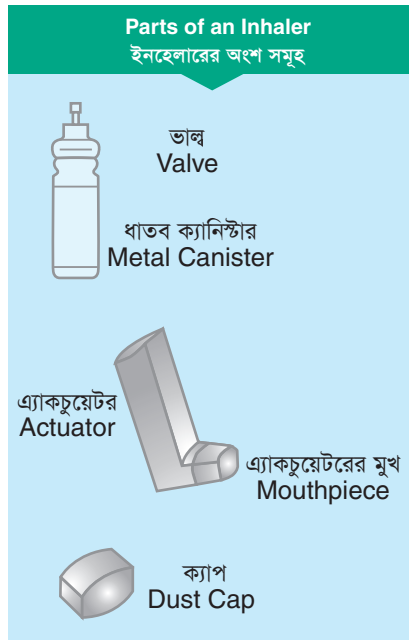
প্রাইম করার জন্য ক্যানিস্টারকে ভালভাবে ঝাঁকিয়ে নিন এবং মুখ থেকে দূরে বাতাসে ৪ বার চাপ দিন এবং প্রতি চাপ দেওয়ার পূর্বে ঝাঁকিয়ে নিন।

Why priming of the inhaler is important?

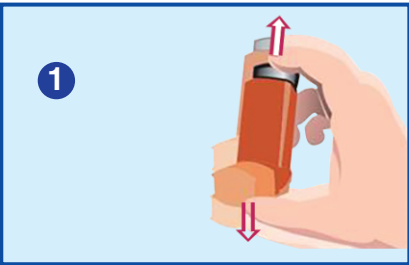
প্রাইম করা প্রয়োজন কেন?

Priming ensures that your inhaler delivers the correct dose. Once primed, your inhaler is ready to use and deliver the correct amount of medicine.

প্রাইমিং আপনার ইনহেলারটির সঠিক ওষুধ সরবরাহ নিশ্চিত করে। প্রাইম হওয়ার সাথে সাথে আপনার ইনহেলারটি ব্যবহার উপযোগী হবে এবং সঠিক মাত্রায় ওষুধ সরবরাহ করবে।

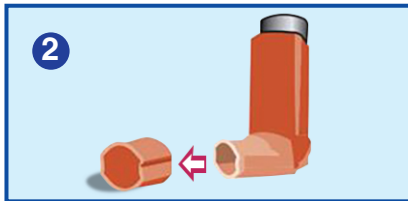


### How to use your inhaler correctly? কিভাবে সঠিক পদ্ধতিতে ইনহেলার ব্যবহার করবেন?



1. Shake the inhaler well before use (3 to 4 times)

চিক্রের মত তর্জনী ও বুড়ো আঙ্গুলের মধ্যে ইনহেলারটি ধরে ৩ থেকে ৪ বার ঝাঁকিয়ে নিতে হবে।



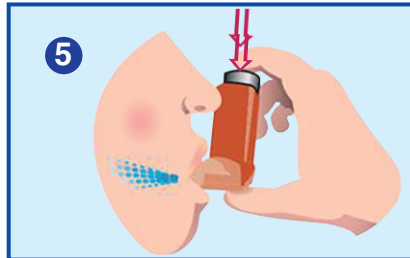
2. Remove the cap from the mouthpiece of the actuator  
এ্যাকচুয়েটরের মাউথপিস থেকে ক্যাপটি সরিয়ে নিন।



3. Breathe out slowly and gently until your lung feels comfortably empty  
মুখ দিয়ে ধীরে ধীরে বাতাস বের করে আপনার ফুসফুসটি খালি করে নিন।



4. Bring the inhaler to your mouth. Place it in your mouth between your teeth and close your mouth around it.  
ইনহেলারটিকে মুখের মধ্যে রাখতে হবে। ইনহেলারের নিঃসরণদ্বার মুখের মধ্যে দাঁতের ফাকে স্থাপন করুন এবং ঠোঁট দিয়ে ফাকা জায়গা বন্ধ করে নিন।



5. Start to breathe in slowly through your mouth. As you start to breathe in, press down firmly on the top of the can to release your medicine, continue to breathe in steadily and deeply.  
মুখ দিয়ে ধীরে ধীরে শ্বাস গ্রহণ করতে হবে এবং একই সময়ে ক্যানিস্টারটিকে চাপ দিতে হবে। এভাবে ধীরে ধীরে গভীরভাবে শ্বাস নেয়ার সময় একটি মাত্রা নিতে হবে।



6. Hold your breath. Remove the inhaler from your mouth. Continue to hold your breath as long as possible, up to 10 seconds.  
শ্বাস ধরে রাখতে হবে। ইনহেলারটিকে মুখ থেকে সরিয়ে ফেলতে হবে। ১০ সেকেন্ড অথবা যতক্ষণ সম্ভব শ্বাস ধরে রাখতে হবে। অতঃপর ধীরে ধীরে শ্বাস ছাড়তে হবে।

### Tips for Children

Children may need assistance of their parents. Children and others who have weaker hands may have difficulty pressing down on the top of the can with just one hand. They can use both hands to make their Inhaler work.

শিশুদের ব্যবহারের জন্য পিতা মাতার সহযোগিতা প্রয়োজন হতে পারে। যাদের হাতে শক্তি কম তাদের ক্ষেত্রে এক হাতে চাপ প্রয়োগ করতে সমস্যা হতে পারে। তারা চাপ প্রয়োগের জন্য দুই হাত ব্যবহার করতে পারেন।

### Notes

If you need another puff of medicine, wait 1 minutes, then repeat step 3 to 6

যদি একাধিক মাত্রা গ্রহণের দরকার হয় তবে কমপক্ষে ১ মিনিট অপেক্ষা করে ৩ থেকে ৬ নং ধাপ পুনরাবৃত্তি করুন।

Rinse your mouth after taking inhaler

ইনহেলার ব্যবহারের পর কুলি করে মুখ পরিষ্কার করে নিন।

### Cleaning of your inhaler

Keeping the plastic actuator clean is very important to prevent medicine buildup and blockage. The actuator should be washed with warm water & shaken to remove excess water and air-dried thoroughly at least once a week. The inhaler may stop spraying if not properly cleaned.

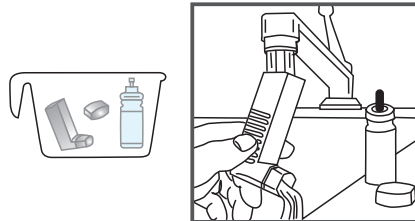
ক্যাপ ও এ্যাকচুয়েটর পরিষ্কার রাখা খুবই গুরুত্বপূর্ণ। ধাতব ক্যানিস্টার থেকে এ্যাকচুয়েটরটা খুলে হালকা গরম পানিতে সপ্তাহে কমপক্ষে একবার ধুয়ে নিতে হবে এবং বাতাসে শুকিয়ে নিতে হবে। ইনহেলার ঠিকমত পরিষ্কার করা না হলে এটা দিয়ে ঠিক মত স্প্রে করা যাবে না।

### Precautions

Pressurised canister, do not puncture, break or incinerate even when apparently empty.  
● Avoid storage in direct sunlight or heat.  
● Store below 30°C.  
● Keep away from eyes.  
● Keep away from children.

### সতর্কতা

চাপযুক্ত ক্যানিস্টার, আপাত দৃষ্টিতে বালি মনে হলেও ছিদ্র করা, ভাঙ্গা অথবা পোড়ানো যাবে না।  
● সরাসরি সূর্যালোক বা তাপ থেকে দূরে রাখুন।  
● ৩০°সে. এর নিচে সংরক্ষণ করুন।  
● চোখের সংস্পর্শে আসতে দেয়া যাবে না।  
● শিশুদের নাগালের বাইরে রাখুন।



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