

# Improvient®

Salbutamol and Ipratropium Bromide

## Description

Improvient® metered dose inhaler is a combination of Salbutamol and Ipratropium Bromide. Salbutamol is a short acting b2 agonist bronchodilator and Ipratropium Bromide is an anticholinergic bronchodilator. When used in combination, they produce greater bronchodilator effect than either agent alone. Improvent® is expected to maximize the response to treatment in patients with chronic obstructive pulmonary disease (COPD) by reducing bronchospasm through two distinctly different mechanisms, anticholinergic (parasympatholytic) and sympathomimetic. Simultaneous administration of both an anticholinergic (Ipratropium Bromide) and a b2 sympathomimetic (Salbutamol Sulphate) is designed to benefit the patient by producing a greater bronchodilator effect than when either drug is utilised alone at its recommended dosage.

## Composition

Improvient® 100/20 mcg HFA Inhaler: Each actuation delivers Salbutamol Sulfate 120.5 mcg equivalent to Salbutamol 100 mcg & Ipratropium Bromide Monohydrate 20.8 mcg equivalent to Ipratropium Bromide 20 mcg.

**Indications:** Improvent® inhalation aerosol is indicated for use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.

## Dosage & administration

The dosage of Improvent should be adapted to the individual requirements of the patient.

Adults (including the elderly and adolescents over 12 years of age): 2 puffs four times a day. Patients may take additional puffs as required; however, the total number of puffs should not exceed 12 puffs in 24 hours.

Children: Not recommended.

## Contraindications

Improvient® inhalation aerosol is contraindicated in patients hypersensitive to any components of the product or to atropine or its derivatives. It is also contraindicated in patients with a history of hypersensitivity to soya lecithin or related food products such as soyabean and peanut.

## Side effects

Salbutamol: Mild tremor and headache have been

rarely reported. These usually disappear with continuous treatment. There have been very rare reports of transient muscle cramp. Hypersensitivity reactions including angio-oedema, urticaria, bronchospasm, hypotension and collapse have been reported very rarely.

Ipratropium: Headache, pain, influenza, chest pain, nausea, bronchitis, dyspnea, coughing, pneumonia, and bronchospasm in lower part, and pharyngitis, sinusitis and rhinitis in the upper part have been reported.

## Precautions

**General:** Iprasol inhalation aerosol contains Ipratropium Bromide and, therefore, it should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy or bladder-neck obstruction.

**Effects seen with sympathomimetic drugs:** Preparations containing sympathomimetic amines such as Salbutamol Sulphate should be used with caution in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus and in patients who are unusually responsive to sympathomimetic amines. B-adrenergic agents may also produce significant hypokalaemia in some patients (possibly through intracellular shunting) which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.

**Use in hepatic or renal disease:** Improvent® inhalation aerosol has not been studied in patients with hepatic or renal insufficiency. It should be used with caution in these patients.

**Paradoxical bronchospasm:** Improvent® inhalation aerosol can produce paradoxical bronchospasm that can be life threatening. If it occurs, the preparation should be discontinued immediately and alternative therapy instituted. It should be recognised that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.

**Cardiovascular effect:** The Salbutamol Sulphate contained in Improvent® inhalation aerosol, like other b adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure and/or other symptoms. Although such effects are uncommon after administration of Improvent® inhalation aerosol at recommended doses, if they occur, discontinuation of the drug may be indicated. In addition, b adrenergic agents have been reported to produce ECG changes, such as flattening of the T wave, prolongation of

the QTc interval, and ST segment depression. Therefore, Improvent® inhalation aerosol should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmia and hypertension. **Immediate hypersensitivity reactions:** Immediate hypersensitivity reactions may occur after administration of Ipratropium Bromide or Salbutamol Sulphate, as demonstrated by rare cases of urticaria, angio-oedema, rash, bronchospasm, anaphylaxis and oropharyngeal oedema.

## Drug interactions

Improvient® inhalation aerosol has been used concomitantly with other drugs, including sympathomimetic bronchodilators, methylxanthines and steroids, commonly used in the treatment of COPD, without adverse drug reactions. No formal drug interaction studies have been performed with Improvent® inhalation aerosol and these drugs or other medications commonly used in the treatment of COPD.

**Anticholinergic agents:** Although Ipratropium bromide is minimally absorbed into the systemic circulation, there is some potential for an additive interaction with concomitantly used anticholinergic medications. Caution is therefore advised in the co-administration of Improvent® inhalation aerosol with other anticholinergic drugs. **B-adrenergic agents:** Caution is advised in the co-administration Improvent® inhalation aerosol and other sympathomimetic agents due to the increased risk of adverse cardiovascular effects. B-receptor blocking agents and Salbutamol inhibit the effect of each other. B-receptor blocking agents should be used with caution in patients with hyperreactive airways.

**Diuretics:** The ECG changes and/or hypokalaemia which may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by b agonists, especially when the recommended dose of the b agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the co-administration of b agonist containing drugs, such as Improvent® inhalation aerosol, with non-potassium sparing diuretics. **Improvient®** inhalation aerosol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants or within two weeks of discontinuation of such agents because the action of Salbutamol on the cardiovascular system may be potentiated.

## Use in pregnancy & lactation

**Pregnancy:** Pregnancy Category C. Improvent®

inhalation aerosol should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

**Lactation:** It is not known whether the components of Improvent® are excreted with breast milk.

## Storage

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

## Packaging

Improvient® 100/20 mcg HFA Inhaler: Each canister contains 200 metered dose inhalations.

## Important Information for the Patients

### Prime your Improvent® Inhaler

Improvient 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 ইম্প্রোভেন্ট 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 পরাক্রমুক 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.

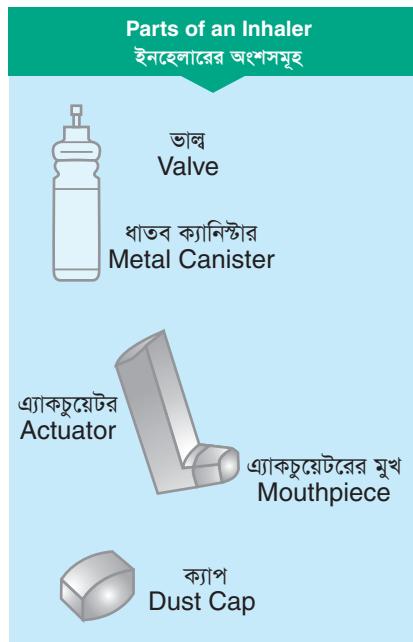
প্রাইম করার জন্য ক্যানিস্টারকে ভালভাবে ঝকিয়ে নিন এবং ৪ বার চাপ দিন এবং প্রতি চাপ দেওয়ার পূর্বে ঝীকাতে হবে।

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

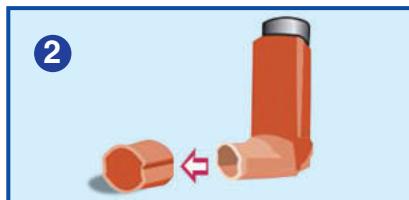


#### How to use your inhaler correctly? কিভাবে সঠিক পদ্ধতিতে ইনহেলার ব্যবহার করবেন?



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

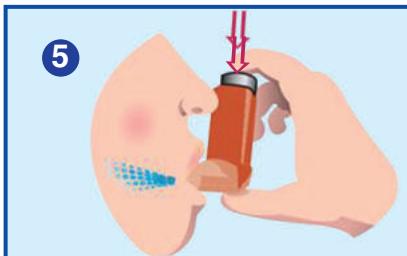
চিন্হের মত তর্জনী ও বুঢ়ো আঙুলের মধ্যে ইনহেলারটি  
ধরে ৩ থেকে ৪ বার বাঁকিয়ে নিতে হবে।



2. Remove the cap from the mouthpiece of the actuator  
একচুটেরের 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।



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। গভীরভাবে শ্বাস  
নেয়ার মাধ্যমে 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 পারে।

#### Notes

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

যদি একাধিক মাত্রা গ্রহনের 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, 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 একচুটের পরিষ্কার রাখা খুবই গুরুত্বপূর্ণ। ধাতব  
ক্যানিস্টার থেকে একচুটেটা খুলে হালকা গরম পানিতে  
সঙ্গাহে কমপক্ষে একবার ধূয়ে 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.

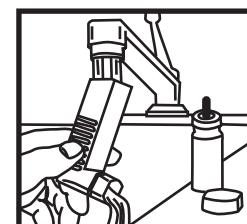
#### সর্তর্কতা

চাপযুক্ত ক্যানিস্টার, আগাম দৃষ্টিতে খালি মনে হলেও ছিন্দ করা, ভাঙা  
অথবা পেডানো যাবে না। সরাসরি সূর্যালোক বা তাপ থেকে দূরে রাখুন।

৩০ ° সে. এর নিচে সংরক্ষণ করুন।

চোখের সংপর্কে আসতে দেয়া যাবে না।

শিশুদের নাগালেনে বাইরে রাখুন।



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