

Attention Health Care Professional:

Detach Patient's Instructions for Use from package insert and dispense with the product.

PROVENTIL[®] HFA

(albuterol sulfate)

Inhalation Aerosol

FOR ORAL INHALATION ONLY

Patient's Instructions for Use

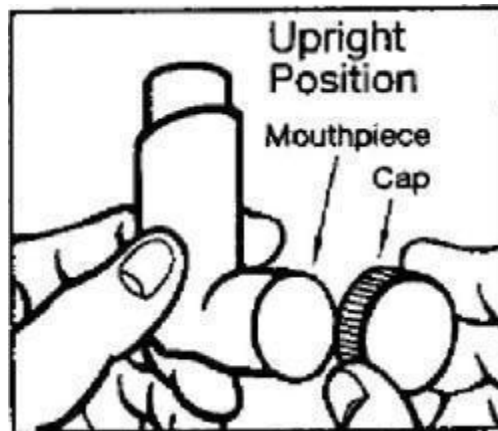


Figure 1

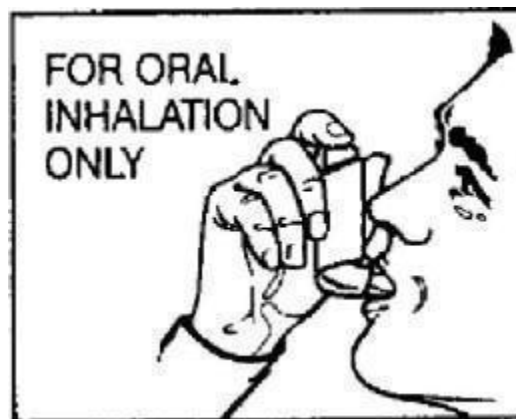



Figure 2

Before using your PROVENTIL[®] HFA (albuterol sulfate) Inhalation Aerosol, read complete instructions carefully. Children should use PROVENTIL HFA Inhalation Aerosol under adult supervision, as instructed by the patient's doctor

Please note that  indicates that this inhalation aerosol does not contain chlorofluorocarbons (CFCs) as the propellant.

1. **SHAKE THE INHALER WELL** immediately before each use. **Then remove the cap from the mouthpiece** (see [Figure 1](#)). **Check mouthpiece for foreign objects prior to use.** Make sure the canister is fully inserted into the actuator.

2. As with all aerosol medications, it is recommended to prime the inhaler before using for the first time and in cases where the inhaler has not been used for more than 2 weeks. Prime by releasing four “test sprays” into the air, away from your face.
3. BREATHE OUT FULLY THROUGH THE MOUTH, expelling as much air from your lungs as possible. Place the mouthpiece fully into the mouth, holding the inhaler in its upright position (see [Figure 2](#)) and closing the lips around it.
4. WHILE BREATHING IN DEEPLY AND SLOWLY THROUGH THE MOUTH, FULLY DEPRESS THE TOP OF THE METAL CANISTER with your index finger (see [Figure 2](#)).
5. HOLD YOUR BREATH AS LONG AS POSSIBLE, up to 10 seconds. Before breathing out, remove the inhaler from your mouth and release your finger from the canister.
6. If your physician has prescribed additional puffs, wait 1 minute, shake the inhaler again, and repeat steps 3 through 5. Replace the cap after use.
7. KEEPING THE PLASTIC MOUTHPIECE CLEAN IS EXTREMELY IMPORTANT TO PREVENT MEDICATION BUILDUP AND BLOCKAGE. THE MOUTHPIECE SHOULD BE WASHED, SHAKEN TO REMOVE EXCESS WATER, AND AIR DRIED THOROUGHLY AT LEAST ONCE A WEEK. INHALER MAY STOP SPRAYING IF NOT PROPERLY CLEANED.

Routine cleaning instructions:

Step 1. To clean, remove the canister and mouthpiece cap. Wash the mouthpiece through the top and bottom with warm running water for 30 seconds at least once a week (see [Figure A](#)). **Never immerse the metal canister in water.**

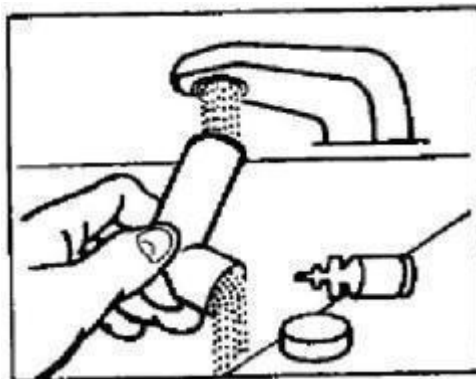


Figure A

Wash mouthpiece under warm running water.

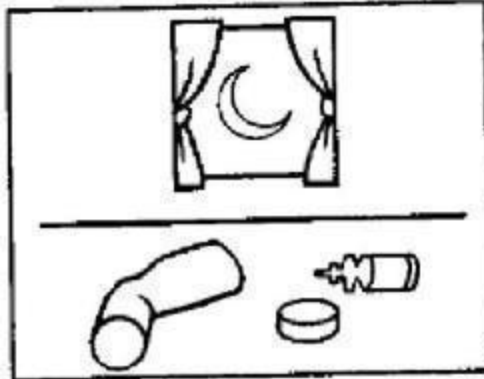


Figure B

Allow mouthpiece to air dry, such as overnight.

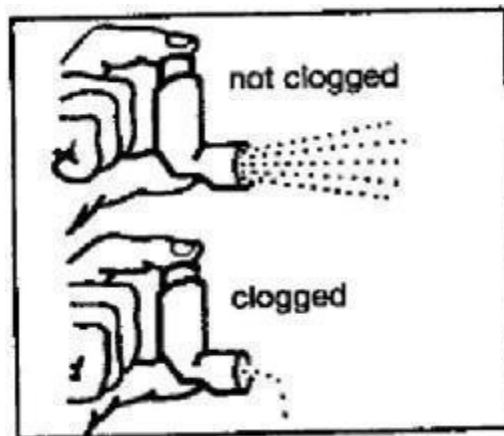


Figure C

When blocked, little or no medicine comes out.

Step 2. To dry, shake off excess water and let the mouthpiece air dry thoroughly, such as overnight (see [Figure B](#)). When the mouthpiece is dry, replace the canister and the mouthpiece cap. Blockage from medication buildup is more likely to occur if the mouthpiece is not allowed to air dry thoroughly.

IF YOUR INHALER HAS BECOME BLOCKED (little or no medication coming out of the mouthpiece, see [Figure C](#)), wash the mouthpiece as described in Step 1 and air dry thoroughly as described in Step 2.

IF YOU NEED TO USE YOUR INHALER BEFORE IT IS COMPLETELY DRY, SHAKE OFF EXCESS WATER, replace the canister, and test spray twice into the air, away from your face, to remove most of the water remaining in the mouthpiece. Then take your dose as prescribed. **After such use, rewash and air dry thoroughly as described in Steps 1 and 2.**

8. The correct amount of medication in each inhalation cannot be assured after 200 actuations, even though the canister is not completely empty. The canister should be

discarded when the labeled number of actuations have been used. Before you reach the specific number of actuations, you should consult your physician to determine whether a refill is needed. Just as you should not take extra doses without consulting your physician, you also should not stop using PROVENTIL HFA Inhalation Aerosol without consulting your physician.

You may notice a slightly different taste or spray force than you are used to with PROVENTIL HFA Inhalation Aerosol, compared to other albuterol inhalation aerosol products.

DOSAGE:

Use only as directed by your physician.

WARNINGS:

The action of PROVENTIL[®] HFA Inhalation Aerosol should last up to 4 to 6 hours. PROVENTIL HFA Inhalation Aerosol should not be used more frequently than recommended. Do not increase the number of puffs or frequency of doses of PROVENTIL HFA Inhalation Aerosol without consulting your physician. If you find that treatment with PROVENTIL HFA Inhalation Aerosol becomes less effective for symptomatic relief, your symptoms become worse, and/or you need to use the product more frequently than usual, medical attention should be sought immediately. While you are taking PROVENTIL HFA Inhalation Aerosol, other inhaled drugs should be taken only as directed by your physician. If you are pregnant or nursing, contact your physician about the use of PROVENTIL HFA Inhalation Aerosol.

Common adverse effects of treatment with PROVENTIL HFA Inhalation Aerosol include palpitations, chest pain, rapid heart rate, tremor, or nervousness. Effective and safe use of PROVENTIL HFA Inhalation Aerosol includes an understanding of the way that it should be administered. Use PROVENTIL HFA Inhalation Aerosol only with the yellow actuator supplied with the product. The PROVENTIL HFA Inhalation Aerosol actuator should not be used with other aerosol medications.

For best results, use at room temperature. Avoid exposing product to extreme heat and cold.

Shake well before use.

Contents Under Pressure.

Do not puncture. Do not store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw container into fire or incinerator. Store between 15° - 25°C (59° - 77°F). **Store the inhaler with the mouthpiece down.** Avoid spraying in eyes. Keep out of reach of children.

Further Information: Your PROVENTIL[®] HFA (albuterol sulfate) Inhalation Aerosol does not contain chlorofluorocarbons (CFCs) as the propellant. Instead, the inhaler contains a hydrofluoroalkane (HFA-134a) as the propellant.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

Developed and Manufactured by:
3M Health Care Limited

Loughborough UK
or
3M Drug Delivery Systems
Northridge, CA 91324, USA

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