- 1 **INSTRUCTIONS FOR USE** 2 PROVENTIL<sup>®</sup> HFA (prō-vent´-il) 3 (albuterol sulfate) 4 Inhalation Aerosol with Dose Indicator 5 6 Read this Instructions for Use before you start using PROVENTIL HFA and each time you get a 7 refill. There may be new information. This information does not take the place of talking to your 8 doctor about your medical condition or treatment. Your doctor should show you how your child 9 should use PROVENTIL HFA. 10 11 Important Information: 12 PROVENTIL HFA is for oral inhalation use only. 13 Take PROVENTIL HFA exactly as your doctor tells you to. 14 PROVENTIL® HFA Inhalation Aerosol comes as a canister with a dose indicator. The dose 15 16 indicator is located on the top of the canister that fits into an actuator (See Figure A). The dose 17 indicator display window will show you how many puffs of medicine you have left. A puff of 18 medicine is released each time you press the center of the dose indicator. 19 20 Do not use the PROVENTIL HFA actuator with a canister of medicine from any other • 21 inhaler. 22 Do not use the PROVENTIL HFA canister with an actuator from any other inhaler. 23
  - Side View Dose Indicator **Top View** Dose indicator display window Pointer Canister Press here Acuator Mouthpiece Cap **Figure A**

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- 27 Before you use PROVENTIL HFA for the first time make sure that the pointer on the dose 28 indicator is pointing to the right of the "200" inhalation mark in the dose indicator display window 29 (See Figure A). 30
- 31 Each canister of PROVENTIL HFA contains 200 puffs of medicine. This does not include the 32 sprays of medicine used for priming your inhaler.
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- The dose indicator display window will continue to move after every 10 puffs.

- 35 The number in the dose indicator display window will continue to change after every 20 • 36 puffs.
- 37 The color in the dose indicator display window will change to red, as shown in the • 38 shaded area, when there are only 20 puffs of medicine left in your inhaler (See Figure 39 B). This is when you need to refill your prescription or ask your doctor if you need 40 another prescription for PROVENTIL HFA.
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Figure B

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45 Priming your PROVENTIL HFA inhaler: 46

- Before using your PROVENTIL HFA for the first time, you should prime your inhaler. If 47 48 you do not use your PROVENTIL HFA for more than 2 weeks, you should re-prime it before 49 use.
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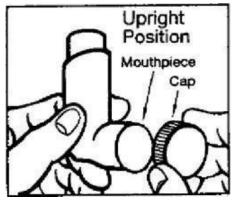
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- Remove the cap from the mouthpiece (See Figure C). Check inside the mouthpiece for • objects before use.
  - Make sure the canister is fully inserted into the actuator. •
- Hold the inhaler in an upright position away from your face and shake the inhaler well. •
- Press down fully on the center of the dose indicator to release a spray of medicine. You • may hear a soft click from the dose indicator as it counts down during use.
- Repeat the priming step 3 more times to release a total of 4 sprays of medicine. Shake • the inhaler well before each priming spray.
- After the 4 priming sprays, the dose indicator should be pointing to 200. There are now • 200 puffs of medicine left in the canister.
  - Your inhaler is now ready to use. •

## 62 63 Using your PROVENTIL HFA inhaler: 64

65 Step 1: Shake the inhaler well before each use. Remove the cap from the mouthpiece (See 66 Figure C). Check inside the mouthpiece for objects before use. Make sure the canister 67 is fully inserted into the actuator.



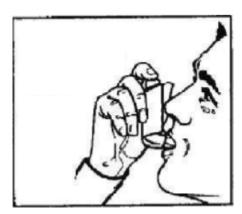
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Figure C

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Step 2: Breathe out as fully as you comfortably can through your mouth. Hold the inhaler in the upright position with the mouthpiece pointing towards you and place the mouthpiece
 fully into the mouth (See Figure D). Close your lips around the mouthpiece.



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- Figure D
- Step 3: While breathing in deeply and slowly, press down on the center of the dose indicator
  with your index finger until the canister stops moving in the actuator and a puff of
  medicine has been released (See Figure D). Then stop pressing the dose indicator.
- Step 4: Hold your breath as long as you comfortably can, up to 10 seconds. Remove the inhaler
  from your mouth, and then breathe out.
- Step 5: If your doctor has prescribed additional puffs of PROVENTIL HFA, wait 1 minute
  then shake the inhaler well. Repeat steps 3 through 5 in the section "Using your
  PROVENTIL HFA inhaler".
- 89 Step 6: Replace the cap right away after use.90
- 91 Cleaning your PROVENTIL HFA inhaler:
- 9293 It is very important that you keep the mouthpiece clean so that medicine will not build up and
- block the spray through the mouthpiece. **Clean the mouthpiece 1 time each week** or if your mouthpiece becomes blocked (**See Figure F**).

## Step 1: Remove the canister from the actuator and take the cap off the mouthpiece. Do not clean the metal canister or let it get wet.

- Step 2: Wash the mouthpiece through the top and bottom with warm running water for 30 seconds (See Figure E).

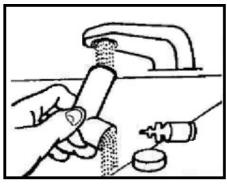
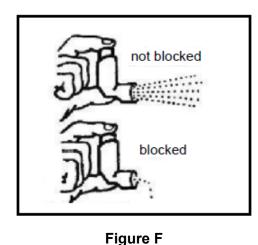


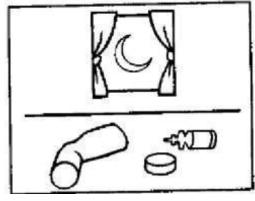
Figure E

Step 3: Shake off as much water from the mouthpiece as you can.

- Step 4: Look in the mouthpiece to make sure any medicine buildup has been completely washed away. If the mouthpiece is blocked with buildup, little to no medicine will come out of the mouthpiece (See Figure F). If there is any buildup, repeat Steps 2 through 4 in the section "Cleaning your PROVENTIL HFA inhaler".



- Step 5: Let the mouthpiece air-dry such as overnight (See Figure G). Do not put the canister
- back into the actuator if it is still wet.



118 119 Figure G 120 121 Step 6: When the mouthpiece is dry, put the canister back in the actuator and put the cap on 122 the mouthpiece. 123 124 If you need to use your PROVENTIL HFA inhaler before it is completely dry, put Note: 125 the canister back in the actuator and shake the inhaler well. Press down on the center 126 of the dose indicator 2 times to release a total of **2 sprays** into the air, away from your 127 face. Take your dose as prescribed then clean and air-dry your inhaler as described in 128 the section "Cleaning your PROVENTIL HFA inhaler". 129 130 How should I store PROVENTIL HFA? 131 • Store PROVENTIL HFA at room temperature between 59°F and 77°F (15°C and 25°C). 132 • Store with the mouthpiece down. 133 Avoid exposing PROVENTIL HFA to extreme heat and cold. 134 Do not puncture or burn the canister. 135 Keep your PROVENTIL HFA inhaler and all medicines out of the reach of children. • 136 Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of MERCK & CO., INC., Whitehouse Station, NJ 08889, USA 137 138 Developed and Manufactured by: 3M Health Care Limited 139 140 Loughborough UK 141 or 142 3M Drug Delivery Systems 143 Northridge, CA 91324, USA 144 Copyright © 1996, 2011, 2012, 2017 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. All rights reserved. 34-8720-1598-6 This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: 09/2017

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