

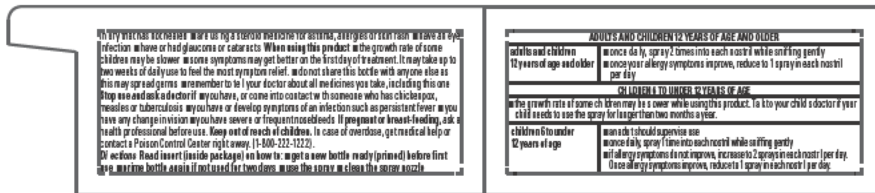
Labeling Format Information: Fonts: REDACTED	
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REDACTED	Description: Ctn Rhinocort Allergy Spray 60 File No.: FDA3010823 Version: E-5 (b) (4)

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COMPOSITE VIEW – FOR REFERENCE ONLY

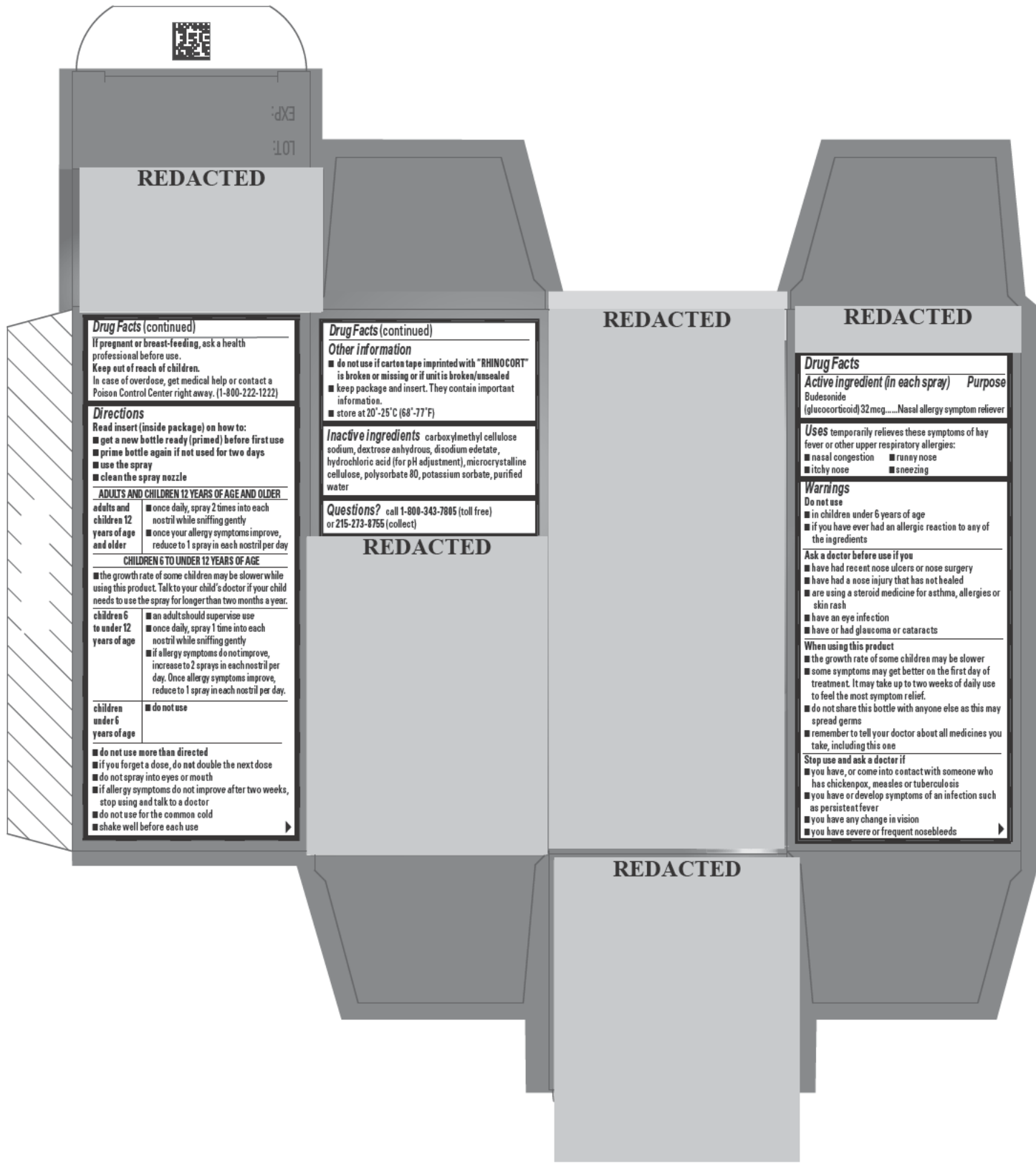


COMPOSITE OUTSIDE VIEW AFTER ASSEMBLY



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Labeling Format Information: Fonts: REDACTED REDACTED	Submission Artwork
REDACTED	Description: <u>Ctn Rhinocort Allergy Spray 120</u> File No.: FDA3010823 Version: A-4 <div style="text-align: right;">(b) (4)</div>

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Labeling Format Information: Fonts:				
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REDACTED				Description: PC Rhinocort Allergy Spray 2x120 File No.: FDA3010823 Version: G-5 (b) (4)

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Labeling Format Information: Fonts:					 Submission Artwork	
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REDACTED		Description: PC Rhinocort Allergy Spray 3x120
File No.:	FDA3010823	Version: D-4
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1. IMPORTANT INFORMATION

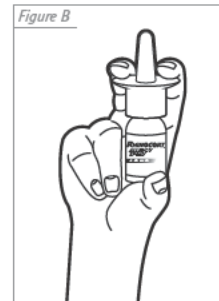
1. Read entire insert before using RHINOCORT® Allergy Spray for complete instructions on how to get a bottle ready for use (primed), how to use the spray bottle, and how to clean the spray nozzle.
2. Keep this insert as it contains important information.



2. STEPS TO GET A BOTTLE READY FOR USE (PRIMED)

Before first use, a new bottle must be primed. To prime RHINOCORT® Allergy Spray:

1. Shake bottle gently.
2. Remove protective cap as shown in Figure A.
3. Hold bottle firmly, as shown in Figure B.



4. Prime the pump by quickly and firmly pressing down on the white collar while holding the base of the bottle with your thumb for 8 sprays. The pump is now ready to use.
5. a. If not used for two consecutive days, reprime the pump until a fine mist appears.
b. If not used for more than 14 days, rinse the spray tip of the pump using the cleaning steps listed in Section 4. After cleaning, reprime until a fine spray appears.

3. INSTRUCTIONS FOR USE

Follow these instructions for daily use of RHINOCORT® Allergy Spray:

1. Gently blow nose to clear nostrils.
2. Shake bottle gently and remove cap.
3. Hold bottle firmly. (See Figure B) Insert spray tip into nostril (tip should not reach far into nose). Close other nostril with a finger and lean head slightly forward so the spray will aim toward the back of nose. (See Figure C) **DO NOT spray towards nasal septum (wall between two nostrils).** (See Figure D)
4. For each spray, press down quickly and firmly on white collar while holding the base of the bottle with your thumb. Breathe gently inward.
5. After spraying into your nostril, lean your head slightly backward for a few seconds.
6. If a second spray is needed in the same nostril, repeat steps 3 through 5. For complete dosing instructions see Table 1 "Directions for Use".
7. Repeat steps 3 through 6, for the other nostril.
8. Avoid blowing your nose for 15 MINUTES after using RHINOCORT® Allergy Spray.
9. Wipe spray tip with a clean tissue (See Figure E), and replace outer cap. Store the bottle in an upright position.

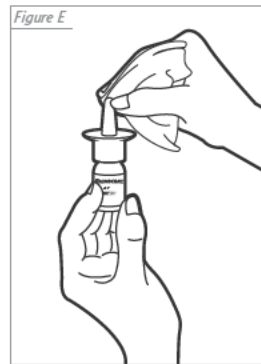


TABLE 1: DIRECTIONS FOR USE

- Before first use, you must get a new bottle ready (primed). See Section 2.
- If bottle is not used for two consecutive days, reprime the pump until a fine spray appears.
- If bottle is not used for more than two weeks, rinse the spray tip of the pump using the cleaning steps listed in Section 4. After cleaning, reprime the pump until a fine spray appears.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER	
adults and children 12 years of age and older	<ul style="list-style-type: none"> ■ once daily, spray 2 times in o each nostril while sniffing gently ■ once your allergy symp oms improve, reduce o 1 spray in each nostril per day

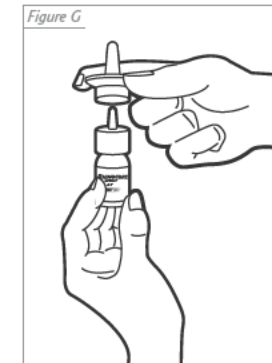
CHILDREN 6 TO UNDER 12 YEARS OF AGE	
■ he g ow h rate of some children may be slower while using his p oduct. Talk o your child's doctor if your child needs to use he spray for longer han wo mon hs a year.	

children 6 to under 12 years of age	<ul style="list-style-type: none"> ■ an adult should supervise use ■ once daily, spray 1 time in o each nostril while sniffing gently ■ if allergy symp oms do not imp ove, increase to 2 sprays in each nostril per day. Once allergy symp oms improve, reduce o 1 pray in each nostril per day.
children under 6 years of age	■ do not use

- Other important information for use**
- do not use more than directed
 - if you forget a dose, do not double he next dose
 - do not spray in o eyes or mou h
 - if allergy symptoms do not imp ove after two weeks, stop using and talk to a doc or
 - do not use for he common cold
 - shake well before each use

4. HOW TO CLEAN YOUR RHINOCORT® ALLERGY SPRAY

Rinse cap and spray tip regularly. To do this:



1. Remove cap and gently pull spray tip away from the bottle. (See Figure G)
2. Wash **only cap and spray tip** in warm water and rinse in cold tap water. Shake to remove excess water.
3. Allow cap and spray tip to air dry completely before reassembling the nasal spray.
4. Press and release spray nozzle until a fine spray is produced, taking care not to spray in the face.
5. If the spray tip becomes blocked, it can be cleared by repeating steps 1 through 3. Do not unblock the nasal applicator with a pin or other sharp object.

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McNeil Submission Artwork

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Description: IFU Rhinocort Allergy Spray
File No.: FDA3010823 Version: C-3

(b) (4)

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/s/

THERESA M MICHELE
03/23/2015