

PATIENT INSTRUCTIONS FOR USE

BRONCHITOL® (mannitol) inhalation powder for oral inhalation use

This Patient Instructions for Use contains information on how to take **BRONCHITOL**.

Each BRONCHITOL box contains:

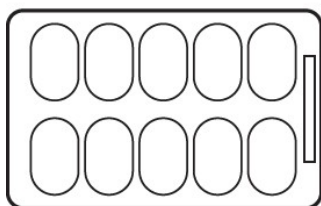
7-day Treatment Pack

- 140 Capsules (14 blister packs)
- 1 Inhaler
- Prescribing Information

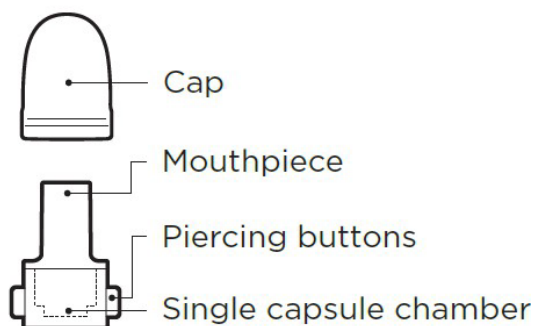
4-week Treatment Pack

- 560 Capsules (56 blister packs)
- 4 Inhalers
- Prescribing Information

Blister Pack



Inhaler



Important Information You Need to Know Before Using BRONCHITOL

- **Do not use BRONCHITOL until your healthcare provider has performed the BRONCHITOL Tolerance Test (BTT) and approved you for treatment.** This is to make sure you get the right treatment if you have a severe reaction.
- **For oral inhalation only**
- **Do not** swallow BRONCHITOL capsules.
- Use an inhaled short-acting bronchodilator 5 to 15 minutes before every dose of BRONCHITOL.
- Use BRONCHITOL **2 times** each day. Inhale through your mouth (oral inhalation) the capsule contents in 10 single BRONCHITOL capsules:
 - **1 time in the morning**
 - **1 time at least 2 to 3 hours before bedtime**

Preparing to use BRONCHITOL

BRONCHITOL is supplied to people in cartons containing 140 or 560 capsules in blister packs.

Supplies you will need to use BRONCHITOL:

- 1 Blister pack
- 1 Inhaler
- Bronchodilator (and spacer for bronchodilator if needed)
- Sink or hand washing station

Before using BRONCHITOL:

Use an inhaled bronchodilator 5 to 15 minutes before using BRONCHITOL (See **Figure A**).



Figure A

Clean and dry hands well (See **Figure B**).



Figure B

Inhaler use steps for inhalation of the contents of a single capsule:

Step 1. Remove cap (See **Figure C**).

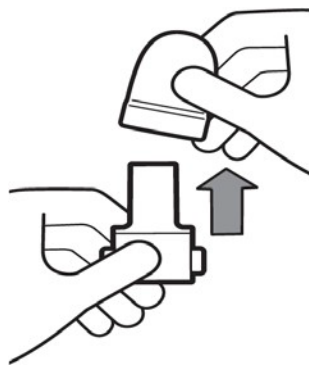


Figure C

Step 2. Twist open inhaler by turning the mouthpiece to the right. (See **Figure D**).

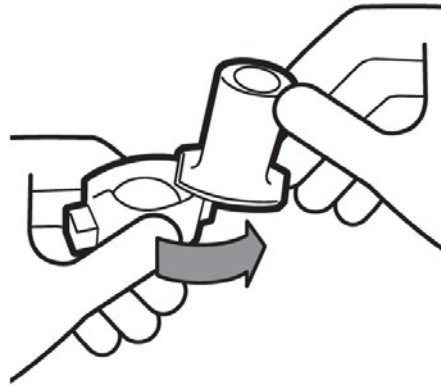


Figure D

Step 3. Take 1 capsule out of the blister pack and put it in the chamber. (See **Figure E**).

Do not place capsule into the mouthpiece of the inhaler.

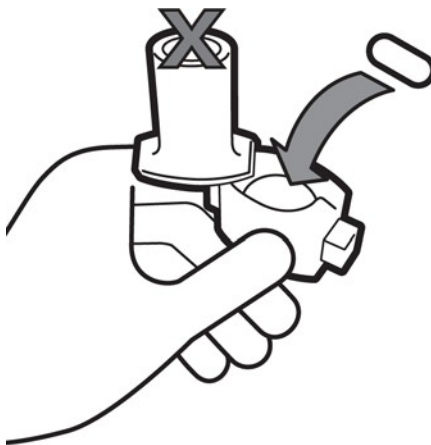


Figure E

Step 4. Hold inhaler upright and turn the mouthpiece to the left until it locks in place. (See **Figure F**).

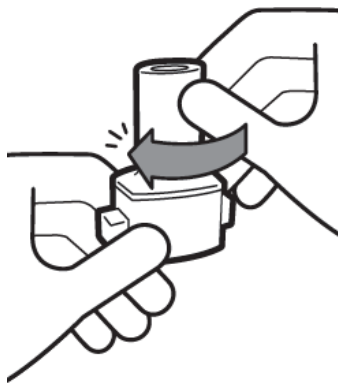


Figure F

Step 5. Push both piercing buttons at the same time. Release both piercing buttons at the same time (See **Figure G**).

Keep inhaler upright. Never keep piercing buttons pressed.

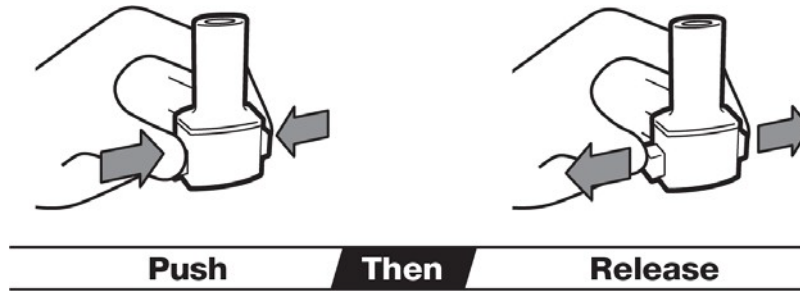


Figure G

Step 6. Breathe out (exhale) fully (See **Figure H**).

Do not breathe out into inhaler.

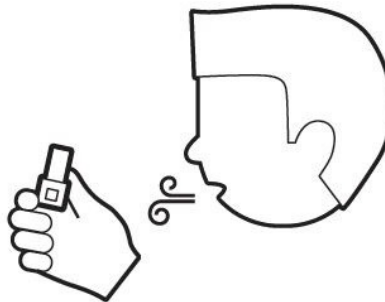


Figure H

Step 7. Close lips around the mouthpiece and take a steady deep breath in through your mouth. **Do not** breathe through your nose. Remove inhaler from mouth. Hold breath for 5 seconds before exhaling, do not breathe out (exhale) into inhaler (See **Figure I**).

You should hear a rattling sound while breathing in. If you do not, tap bottom of inhaler firmly and repeat steps 6 and 7.

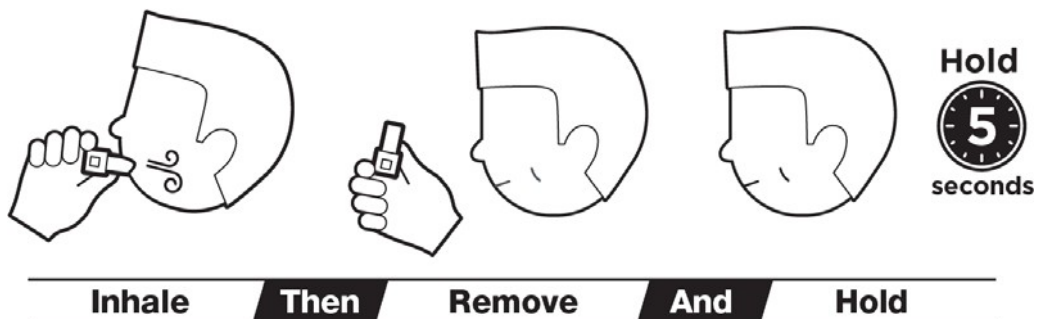


Figure I

Step 8. Open the inhaler by turning the cap to the right. If powder is left in capsule, repeat steps 6 and 7. After the capsule is empty, throw away. (See **Figure J**).

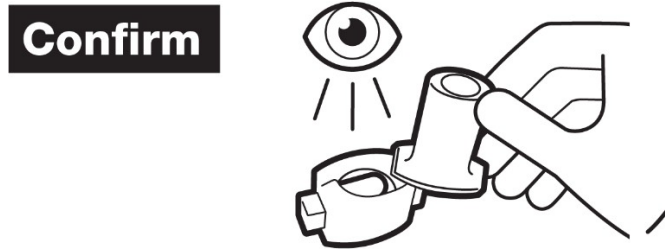


Figure J

Step 9. Repeat steps 3 to 8 for all 10 capsules in 1 blister pack (See **Figure K**).

Breathe in (inhale) contents of each capsule one after another until all 10 capsules in the blister pack are used.

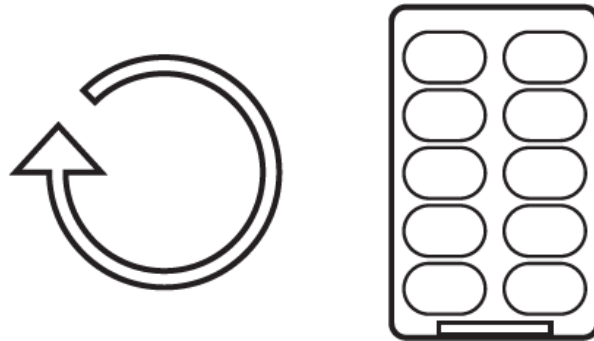


Figure K

Step 10. After inhaling contents of all 10 capsules, close mouthpiece and place cap on inhaler (See **Figure L**).

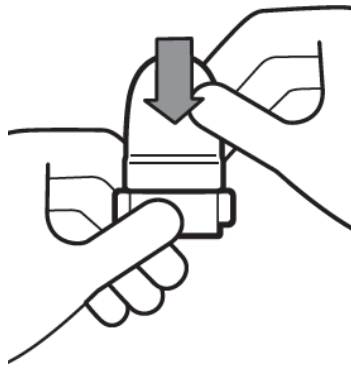


Figure L

Step 11. Continue using BRONCHITOL for 7 days then throw away (discard) the inhaler (See **Figure M**).

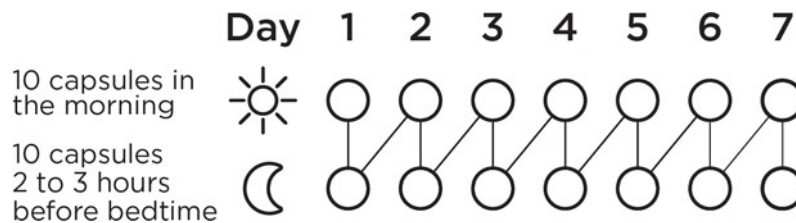


Figure M

How should I store BRONCHITOL?

- Store BRONCHITOL at room temperature between 68°F to 77°F (20°C to 25°C).
- If your BRONCHITOL capsules are stored at temperatures more than 86°F (30°C), throw them away.
- Do not freeze BRONCHITOL.
- Do not refrigerate BRONCHITOL.
- **Keep BRONCHITOL and all medicines out of the reach of children.**

Cleaning your BRONCHITOL inhaler.

- Your inhaler should give you the correct dose of medicine for 7 days without needing cleaning. However, if your inhaler does need cleaning:
 - Make sure your inhaler is empty.
 - Wash your inhaler in warm water with the mouthpiece open.
 - Shake it until there are no large water droplets left in the inhaler.
 - Leave it to dry in the air by laying it on its side with the mouthpiece open.
 - Allow the inhaler to dry fully (or completely) after it has been washed.

Caring for your BRONCHITOL inhaler.

- Keep your inhaler dry and always make sure your hands are completely dry before using it.
- **Do not** breathe or cough into your inhaler.
- **Do not** take your inhaler apart.
- **Do not** place a capsule directly into the mouthpiece of your inhaler.
- **Do not** leave a used capsule in your inhaler chamber.
- Use a new inhaler after 7 days.
- If your inhaler breaks, call to your healthcare provider.

For more information about BRONCHITOL or how to use your inhaler, call 1-888-276-2144.

Manufactured by:
Arna Pharma Pty Ltd.

20 Rodborough Road
Frenchs Forest NSW
2086 AUSTRALIA

Manufactured for:
Pharmaxis Europe Limited
108 Q House Furze Road,
Sandyford Dublin 18,
D18AY29 Ireland
1-888-276-2144

BRONCHITOL is registered in the US Patent and Trademark Office.

This Patient Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 06/2024