

# HEALTHCARE PRACTITIONER INSTRUCTIONS FOR USE

**Bronchitol**<sup>®</sup>  
(mannitol) inhalation powder

40 mg per capsule  
FOR ORAL INHALATION ONLY

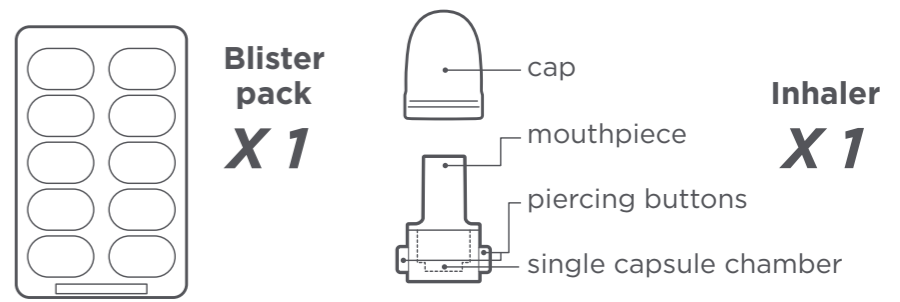
## BRONCHITOL Tolerance Test (BTT)

The BTT identifies patients who are hyperresponsive to BRONCHITOL (inhaled mannitol) through a series of monitored inhalations of increasing doses. The BTT must be performed by a healthcare provider who is able to manage acute bronchospasm.

**STOP the BTT if the patient:**

- Has SpO<sub>2</sub> or FEV<sub>1</sub> measurements that fall below the STOP values calculated in STEP A
- Shows any signs of significant bronchoconstriction requiring treatment with a bronchodilator, such as wheezing or shortness of breath
- Experiences a distressing cough, vomiting, or any other signs that they are not tolerating BRONCHITOL
- Has **not** inhaled the contents of a total of 10 capsules during STEPS C through F; schedule a repeat BTT

## BRONCHITOL Tolerance Test carton includes:



Start here and record values below.

**STEP A Pre-assessment calculations**

Measure baseline SpO <sub>2</sub> and FEV <sub>1</sub> values.	Today's baseline	STOP values
	SpO <sub>2</sub> : _____% x 0.9 = _____%	<b>90-STOP</b> (90% of baseline SpO <sub>2</sub> )
Calculate STOP values.	FEV <sub>1</sub> : _____L x 0.8 = _____L	<b>80-STOP</b> (80% of baseline FEV <sub>1</sub> )

**STEP B** Instruct patient to use an inhaled short-acting beta-agonist. **WAIT 5-15 minutes** While waiting:  
 Instruct patient to wash and dry hands.  
 Review all inhaler use steps.

**STEP C** Follow steps 1-8 on the right. Instruct patient to inhale contents of 1 capsule. Open inhaler, **CONFIRM** powder has been inhaled. **WAIT 1 minute** Record new SpO<sub>2</sub>.  
 SpO<sub>2</sub>: \_\_\_\_\_%  
 Is new SpO<sub>2</sub> more than **90-STOP**?  
 YES NO

**STEP D** Follow steps 3-8 on the right. Instruct patient to inhale contents of 2 capsules, one capsule at a time. Open inhaler, **CONFIRM** powder has been inhaled. **WAIT 1 minute** Record new SpO<sub>2</sub> and new FEV<sub>1</sub>.  
 SpO<sub>2</sub>: \_\_\_\_\_%  
 FEV<sub>1</sub>: \_\_\_\_\_L  
 New SpO<sub>2</sub> is more than **90-STOP**?  
 New FEV<sub>1</sub> is more than **80-STOP**?  
 YES to both NO to either

**STEP E** Follow steps 3-8 on the right. Instruct patient to inhale contents of 3 capsules, one capsule at a time. Open inhaler, **CONFIRM** powder has been inhaled. **WAIT 1 minute** Record new SpO<sub>2</sub> and new FEV<sub>1</sub>.  
 SpO<sub>2</sub>: \_\_\_\_\_%  
 FEV<sub>1</sub>: \_\_\_\_\_L  
 New SpO<sub>2</sub> is more than **90-STOP**?  
 New FEV<sub>1</sub> is more than **80-STOP**?  
 YES to both NO to either

**STEP F** Follow steps 3-8 on the right. Instruct patient to inhale contents of 4 capsules, one capsule at a time. Open inhaler, **CONFIRM** powder has been inhaled. **WAIT 1 minute** Record new SpO<sub>2</sub> and new FEV<sub>1</sub>.  
 SpO<sub>2</sub>: \_\_\_\_\_%  
 FEV<sub>1</sub>: \_\_\_\_\_L  
 New SpO<sub>2</sub> is more than **90-STOP**?  
 New FEV<sub>1</sub> is more than **80-STOP**?  
 YES to both NO to either

The patient has passed the BTT. **BRONCHITOL** may be prescribed.

The recommended dosage of BRONCHITOL is 400 mg twice a day. This requires the inhalation of the contents of 10 capsules (blister pack x 1) twice a day.

**STOP** The patient has failed the BTT. **DO NOT** continue the BTT. **DO NOT** prescribe BRONCHITOL.

Wait 15 minutes, then monitor SpO<sub>2</sub> and FEV<sub>1</sub> to confirm recovery to baseline. Treat bronchospasm as needed.

### Ensure you have ready

- BRONCHITOL Tolerance Test carton
- Bronchodilator (and spacer if needed)
- Timer
- Spirometer and nose clip
- Pulse oximeter
- Calculator
- Rescue medication and resuscitation equipment
- Sink/hand washing station
- Glass of water for patient to sip during BTT, if necessary
- Pen to record values
  - Color in capsules to keep track of how many have been administered

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

- 1** Remove cap.
- 2** Twist open inhaler by turning the mouthpiece.
- 3** Take 1 capsule out of the package and put it in the chamber. **Do not put capsule into the mouthpiece.**
- 4** Hold inhaler upright and turn the mouthpiece until it locks in place.
- 5** **PUSH THEN RELEASE**  
 Push both buttons at the same time. **Keep the inhaler upright.**  
 Release both buttons at the same time. **Never keep buttons pressed.**
- 6** Exhale fully (do not exhale into inhaler).
- 7** **INHALE THEN REMOVE AND HOLD**  
 Close lips around mouthpiece and take a steady deep breath. **Remove inhaler from mouth.**  
**Hold breath for 5 seconds before exhaling (do not exhale into inhaler).**  
**Hold 5 seconds**  
 You should hear a rattling sound while breathing in. If you do not, tap bottom of inhaler firmly and repeat steps 6 and 7.
- 8 CONFIRM**  
 Open inhaler. If powder is left in capsule, repeat steps 6 and 7. Once empty, throw capsule away.