

Tiotropium Bromide
Inhalation Powder Capsule

Directions for use



This guide supports the **Instructions for Use** found in the Package Insert with more images and helpful tips. This information does not take the place of talking to your doctor about your medical condition or your treatment. Please read the **Instructions for Use** before you take your medicine.

Important Information:

- **DO NOT** swallow the tiotropium capsules
- The Lupin tiotropium capsules should only be used with the LupinHaler device and inhaled through your mouth (oral inhalation)
- **DO NOT** take any other medicine with your LupinHaler device



FOR MORE RESOURCES, VISIT OUR WEBSITE

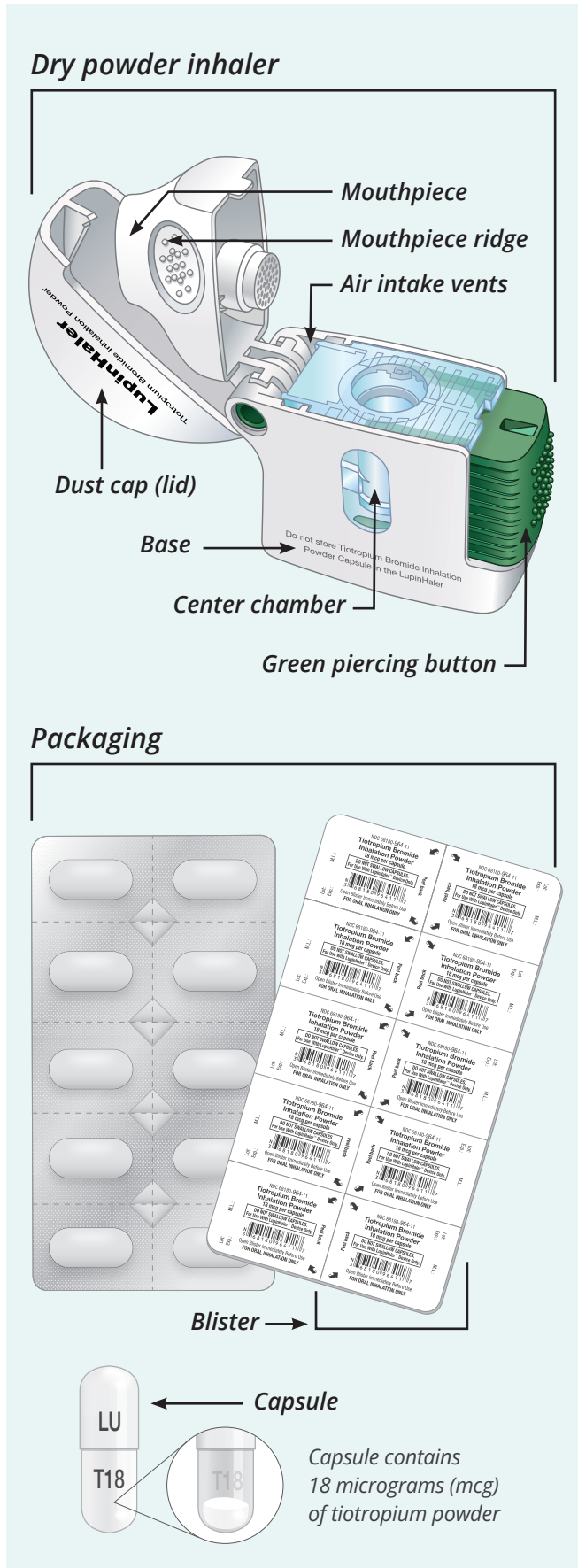


To watch instructional videos and find answers to commonly asked questions, visit Lupin.com/LupinHalerSupport or scan this QR code.

Need to connect with the Lupin team?

Please call 1-800-399-2561 from 8:00 AM to 5:00 PM EST, Monday through Friday, to speak with a Lupin team member.

GET TO KNOW YOUR LUPINHALER DEVICE AND TIOTROPIUM CAPSULES



Your LupinHaler

Dry powder inhaler:

This device is designed to deliver contents from a capsule to the lungs

Dust cap (lid):

This covers the mouthpiece and protects it from dust or other things getting inside

Mouthpiece:

This part of the dry powder inhaler goes in your mouth when you are ready to inhale your medicine

Mouthpiece ridge:

This is the raised edge on the side of the mouthpiece

Base:

This is the bottom of the dry powder inhaler

Green piercing button:

This button pierces (makes holes in) a capsule – this allows you to inhale the medicine through your mouth. The button can also open the dust cap and inner part of the base of the dry powder inhaler

Center chamber:

This part of the dry powder inhaler holds the capsule

Air intake vents:

These openings allow your breath to move through the dry powder inhaler. Dry powder inhalers are activated by breathing in

Your tiotropium capsules

Packaging:

Each capsule is packaged in a blister

Capsule:

Each capsule contains a dry powder form of tiotropium bromide and lactose for inhalation (the action of inhaling or breathing in). The capsules are designed to fit your LupinHaler. Each capsule contains a small amount of powder (as seen in the image of the capsule). This is one full dose of medicine

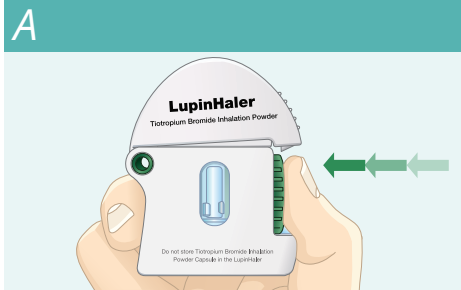
- Do not open the capsules, or they may not work
- Do not swallow the capsules



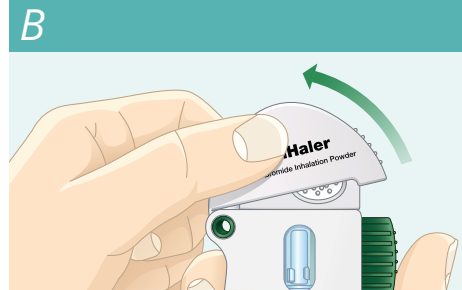
STEPS FOR FIRST-TIME USERS- TAKING YOUR FULL DAILY DOSE

Taking your full daily dose of medicine requires several steps. After removing your LupinHaler device from the pouch...

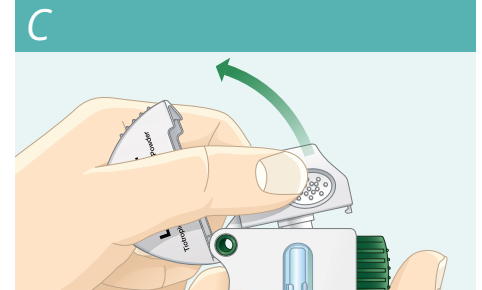
Step 1 – Open your LupinHaler



Open the dust cap by pressing the green piercing button



Pull the dust cap upward, away from the base to see the mouthpiece

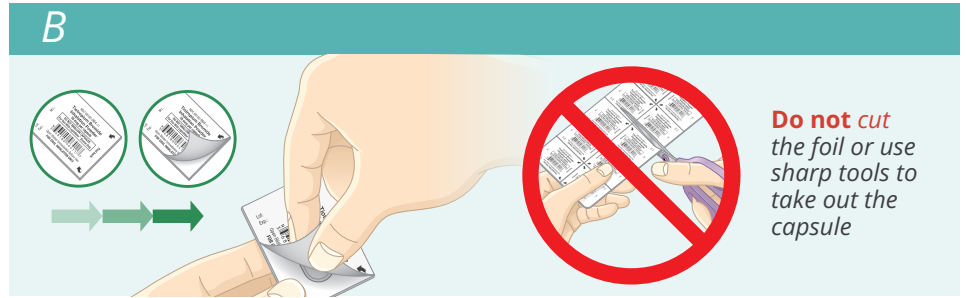


Pull the mouthpiece ridge up and away from the base to see the center chamber

Step 2 – Insert the capsule into your LupinHaler

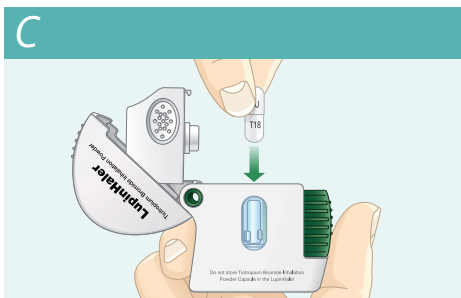


Separate only one of the blisters from the blister package by tearing along the perforated line

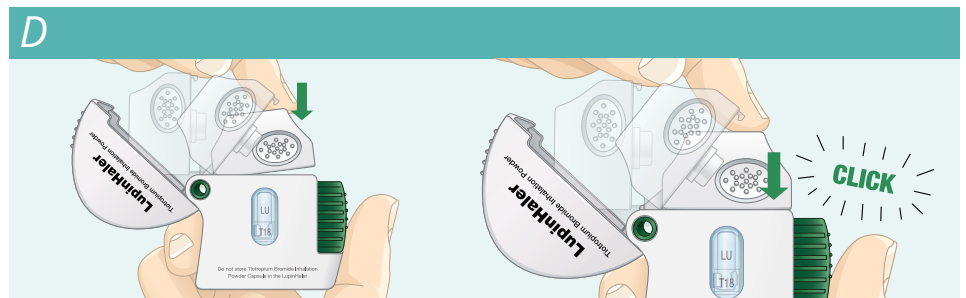


Remove the tiotropium capsule from the blister:

- Bend one of the blister corners with an arrow and separate the aluminum foil layers
- Peel back the printed foil until you see the whole capsule
- **Do not** cut the foil or use sharp tools to take out the capsule from the blister. Sharp tools may damage the capsule



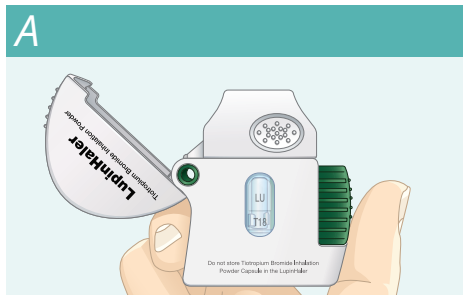
Place the capsule in the center chamber of your LupinHaler



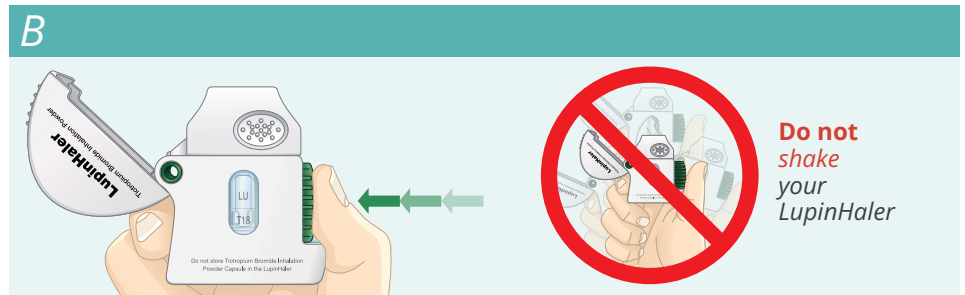
Close the mouthpiece firmly against the white base until you hear a click. Leave the dust cap open

STEPS FOR FIRST-TIME USERS- TAKING YOUR FULL DAILY DOSE (CONT.)

Step 3 – Pierce the capsule



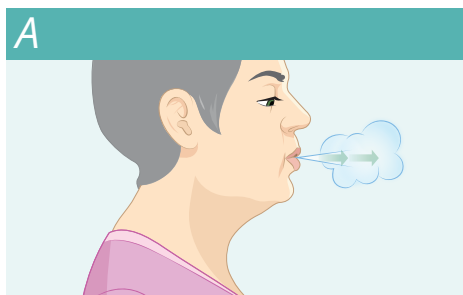
Hold your LupinHaler with the mouthpiece pointed up



Press the green piercing button once until it is flat (flush) against the base, then release

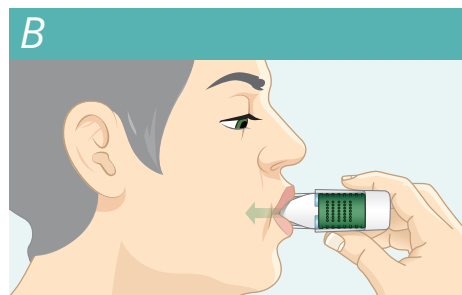
- **Important information** – **Do not** press the green piercing button more than one time
- **Do not** shake your LupinHaler

Step 4 – Take your full daily dose (two breaths in from the same capsule)



Breathe out completely in one breath to empty your lungs of any air

- **Do not** breathe into your LupinHaler



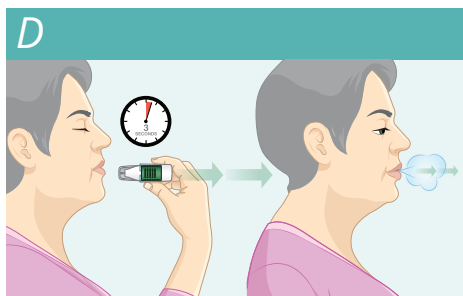
Hold your head in an upright position while you are looking straight ahead. Raise your LupinHaler to your mouth in a horizontal position

- **Do not** block the air intake vents



Close your lips tightly around the mouthpiece. **Breathe in deeply until your lungs are full**

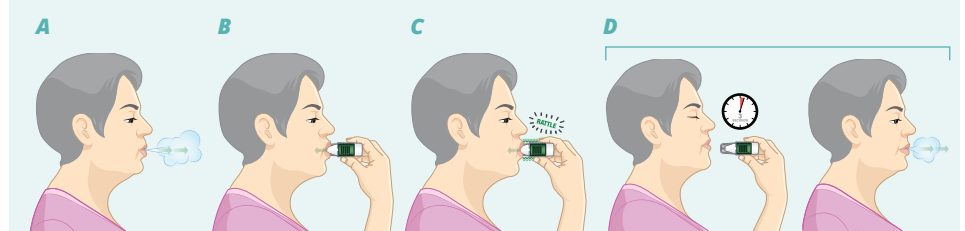
- When you breathe in, you should **hear or feel the capsule vibrate (rattle)**
- The rattle tells you that you breathed in correctly



Hold your breath for a few seconds and, at the same time, take your LupinHaler out of your mouth

- After a few seconds, breathe normally again

Repeat Step 4



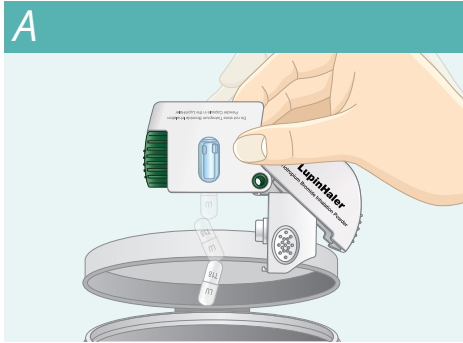
• **To get your full daily dose (two breaths in from the same tiotropium capsule), repeat step 4**

- **Do not** press the green piercing button again

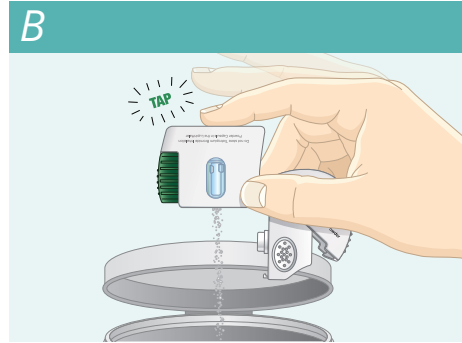
STEPS FOR FIRST-TIME USERS- TAKING YOUR FULL DAILY DOSE (CONT.)

After you take your full daily dose, it is important to take care of your LupinHaler.

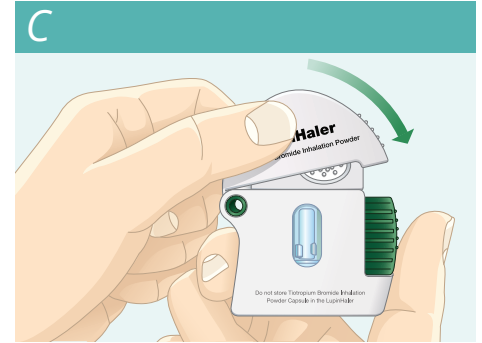
Step 5 – Prepare your LupinHaler for storage



Open the mouthpiece and tip out the used capsule into your trash can, without touching it



Remove any capsule pieces or buildup by turning your LupinHaler upside down and tapping it



Close the mouthpiece and dust cap for storage

Remember:

- **Do not swallow the tiotropium capsules**
- To get your full medicine dose each day, you must breathe in two times from the same tiotropium capsule
- Piercing the tiotropium capsule may produce small pieces of the capsule. When you breathe in your medicine, some of these pieces may pass through your LupinHaler into your mouth or throat. This is normal. The small pieces of the capsule should not harm you
- If you open more than one blister when preparing for your daily dose by mistake, throw the extra capsule away. **Do not** use the extra capsule
- Keep your LupinHaler and capsules away from:
 - damp or moist places
 - extreme hot and cold temperatures

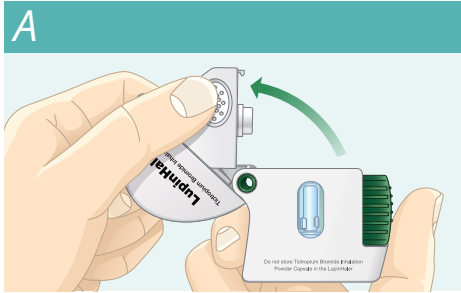


Do not swallow
the tiotropium capsules

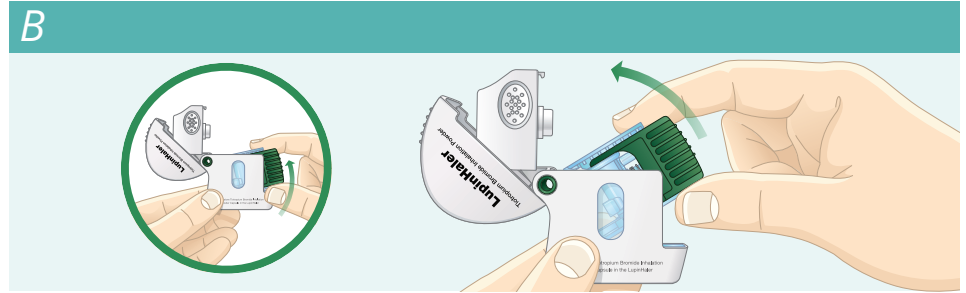
STEPS FOR CLEANING YOUR LUPINHALER DEVICE

You may clean your LupinHaler as needed. Cleaning it requires several steps.

Step 1 – Open your LupinHaler

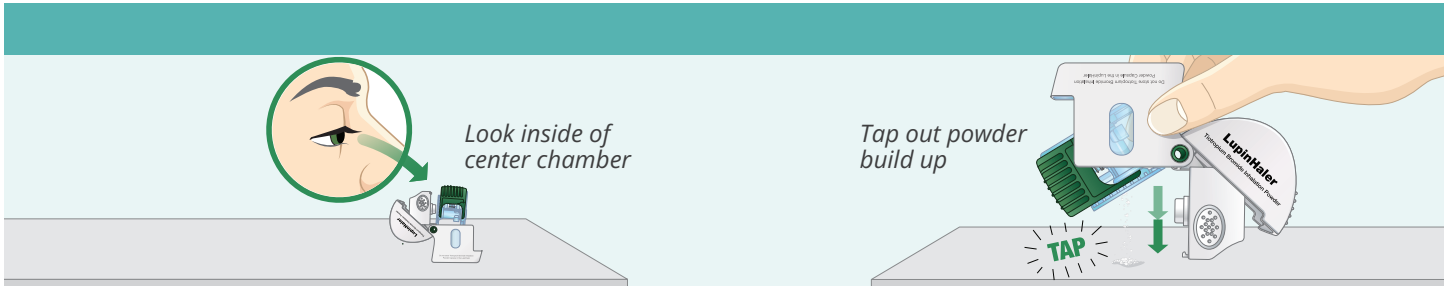


Open the dust cap and mouthpiece



Open the inner part of the base by lifting the green piercing button

Step 2 – Look in the center chamber



Look in the center chamber for tiotropium capsule pieces or powder buildup. If seen, tap out

Step 3 – Rinse your LupinHaler



Rinse your LupinHaler with warm water while you also press the green piercing button a few times.

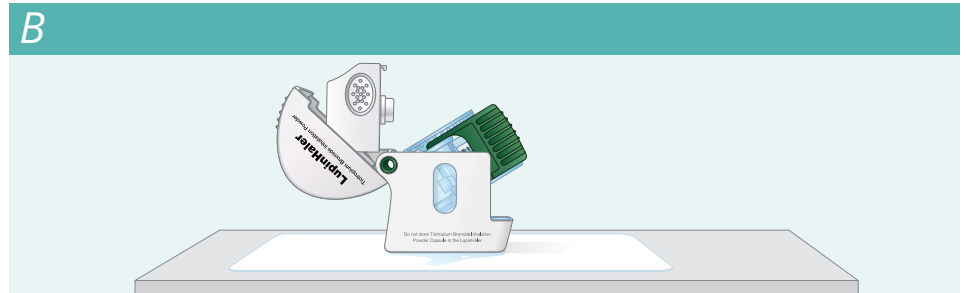
- Pressing the green piercing button will allow the water to clean the center chamber and the piercing needle
- Check that any remaining powder buildup or capsule pieces are removed

STEPS FOR CLEANING YOUR LUPINHALER DEVICE (CONT.)

Step 4 – Dry your LupinHaler



Dry your LupinHaler well by tipping the excess water out on a paper towel



Leave the dust cap, mouthpiece, and base open by fully spreading the LupinHaler out so that all parts can air dry for 24 hours

Remember:

- **Do not** use cleaning agents or detergents
- **Do not** place your LupinHaler in the dishwasher for cleaning
- **Do not** use a hair dryer to dry your LupinHaler
- **Do not** use your LupinHaler when it is wet. If needed, you may clean the outside of the mouthpiece with a clean, damp cloth

SIMPLE TIPS FOR THE LUPINHALER DEVICE



DO

- **Do** use your Lupin tiotropium capsules with your LupinHaler
- **Do** check the center chamber for buildup; if there is any, tap out before use
- **Do** press the green piercing button once until it is flat (flush) against the base
- **Do** breathe out completely before each of the two inhalations
- **Do** close the dust cap after every daily use
- **Do** clean your LupinHaler as needed
- **Do** let your LupinHaler air dry for 24 hours



DO NOT

- **Do not** breathe out into your LupinHaler
- **Do not** use your LupinHaler with other types of medicine
- **Do not** clean your LupinHaler with anything other than warm water
- **Do not** use your LupinHaler if it is wet
- **Do not** store your LupinHaler and medicine in extreme hot and cold temperatures

APPROVED USE

Tiotropium bromide inhalation powder is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Tiotropium bromide inhalation powder is also indicated to reduce exacerbations in COPD patients.

IMPORTANT SAFETY INFORMATION

- **Do not use tiotropium bromide inhalation powder if you** are allergic to tiotropium, ipratropium or similar drugs, or any ingredient in these medicines.
 - **Tiotropium bromide inhalation powder is not a rescue medicine and should not be used for treating sudden breathing problems.** Your doctor may give you other medicine to use for sudden breathing problems.
 - Before using tiotropium bromide inhalation powder, tell your doctor if you have a severe allergy to milk proteins.
 - Tiotropium bromide inhalation powder can cause serious side effects, including:
 - **Allergic reaction.** Symptoms may include:
 - raised red patches on your skin (hives)
 - itching
 - rash
 - swelling of the lips, tongue, or throat that may cause difficulty in breathing or swallowing
 - **Sudden narrowing and blockage of the airways into the lungs (bronchospasm).** Your breathing suddenly gets worse.
 - **New or worsened increased pressure in the eyes (acute narrow-angle glaucoma).** Symptoms of acute narrow-angle glaucoma may include:
 - eye pain
 - blurred vision
 - seeing halos (visual halos) or colored images along with red eyesUsing only eye drops to treat these symptoms may not work.
 - **New or worsened urinary retention.** Symptoms of blockage in your bladder and/or enlarged prostate may include: difficulty passing urine, painful urination.
- If you have any of these symptoms, stop taking tiotropium bromide inhalation powder and call your doctor right away.
- The most common side effects reported with tiotropium bromide inhalation powder in patients with COPD include sore throat, cough, dry mouth, and sinus infection.
 - Other side effects with tiotropium bromide inhalation powder include:
 - upper respiratory tract infection
 - dry mouth
 - sinus infection
 - sore throat
 - non-specific chest pain
 - urinary tract infection
 - indigestion
 - runny nose
 - constipation
 - increased heart rate
 - blurred vision
- **Do not swallow tiotropium bromide inhalation powder capsules.**
 - **The contents of the capsule should only be inhaled through your mouth using the LupinHaler device.**
 - **Do not use the LupinHaler device to take any other medicine.**
 - Do not let the powder from the tiotropium bromide inhalation powder capsule get into your eyes. Your vision may get blurry and the pupil in your eye may get larger (dilate). If this happens, call your doctor.
 - Tiotropium bromide inhalation powder can cause dizziness and blurred vision. Should you experience these symptoms you should use caution when engaging in activities such as driving a car or operating appliances or other machines.
 - These are not all the possible side effects with tiotropium bromide inhalation powder. Tell your doctor if you have any side effect that bothers you or that does not go away.
- Call your doctor for medical advice about side effects. You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
- Read the “Instructions for Use” for Tiotropium Bromide Inhalation Powder before you use your inhaler. Talk with your doctor if you do not understand the instructions.
- For more information about tiotropium bromide inhalation powder, visit our website at www.lupinpharmaceuticals.com, or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.
- Please see the full Prescribing Information, including Instructions for Use, for Tiotropium Bromide Inhalation Powder.**

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