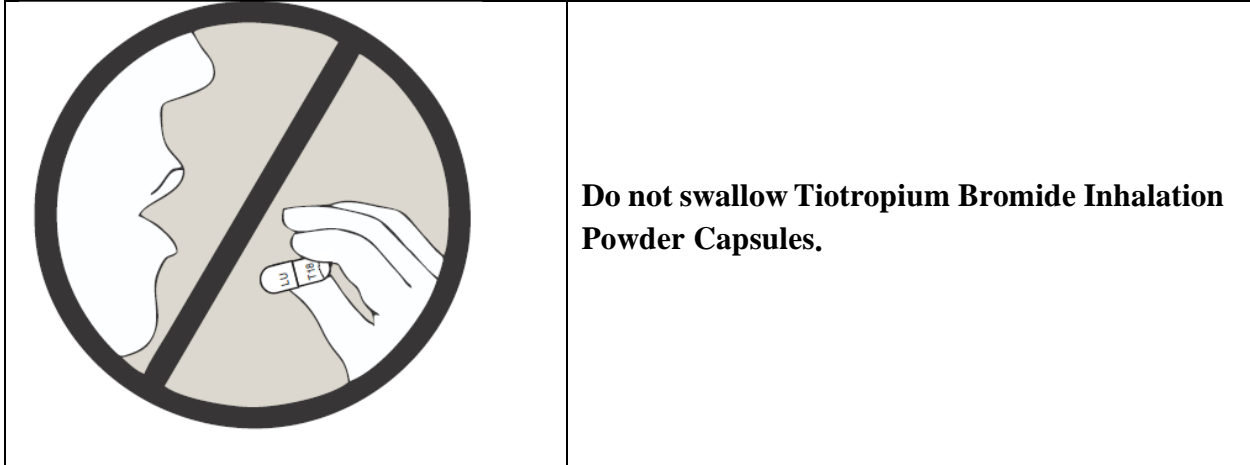


TABLE OF CONTENTS

PATIENT INFORMATION	2
What is tiotropium bromide inhalation powder?	2
Who should not take tiotropium bromide inhalation powder?	3
What should I tell my doctor before using tiotropium bromide inhalation powder?.....	3
How should I take tiotropium bromide inhalation powder?	4
What should I avoid while using tiotropium bromide inhalation powder?	4
What are the possible side effects of tiotropium bromide inhalation powder?.....	4
How do I store tiotropium bromide inhalation powder?.....	5
General information about tiotropium bromide inhalation powder	6
What are the ingredients in tiotropium bromide inhalation powder?	6
INSTRUCTIONS FOR USE	7

PATIENT INFORMATION

Tiotropium Bromide Inhalation Powder (tye-oh-TROE-pee-um BROE-mide)



Important Information: Do not swallow tiotropium bromide inhalation powder capsules. Tiotropium bromide inhalation powder capsules should only be used with the LupinHaler™ device and inhaled through your mouth (oral inhalation).

Read the information that comes with your tiotropium bromide inhalation powder before you start using it and each time you refill your prescription. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is tiotropium bromide inhalation powder?

- Tiotropium bromide inhalation powder is a prescription medicine used each day (a maintenance medicine) to control symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
- Tiotropium bromide inhalation powder helps make your lungs work better for 24 hours. Tiotropium bromide inhalation powder relaxes your airways and helps keep them open. You may start to feel like it is easier to breathe on the first day, but it may take longer for you to feel the full effects of the medicine. Tiotropium bromide inhalation powder works best and may help make it easier to breathe when you use it every day.
- Tiotropium bromide inhalation powder reduces the likelihood of flare-ups and worsening of COPD symptoms (COPD exacerbations). A COPD exacerbation is defined as an increase or new onset of more than one COPD symptom such as cough, mucus, shortness of breath, and wheezing that requires medicine beyond your rescue medicine.

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.

It is not known if tiotropium bromide inhalation powder is safe and effective in children.

Who should not take tiotropium bromide inhalation powder?

Do not use tiotropium bromide inhalation powder if you:

- are allergic to tiotropium, ipratropium (Atrovent[®]), or any of the ingredients in tiotropium bromide inhalation powder. See the end of this leaflet for a complete list of ingredients in tiotropium bromide inhalation powder.

Symptoms of a serious allergic reaction to tiotropium bromide inhalation powder may include:

- raised red patches on your skin (hives)
- itching
- rash
- swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing

If you have these symptoms of an allergic reaction, stop taking tiotropium bromide inhalation powder and call your doctor right away or go to the nearest hospital emergency room.

What should I tell my doctor before using tiotropium bromide inhalation powder?

Before taking tiotropium bromide inhalation powder, tell your doctor about all your medical conditions, including if you:

- have kidney problems.
- have glaucoma. Tiotropium bromide inhalation powder may make your glaucoma worse.
- have an enlarged prostate, problems passing urine, or a blockage in your bladder. Tiotropium bromide inhalation powder may make these problems worse.
- are pregnant or plan to become pregnant. It is not known if tiotropium bromide inhalation powder could harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if tiotropium bromide passes into breast milk. You and your doctor will decide if tiotropium bromide inhalation powder is right for you while you breast-feed.
- have a severe allergy to milk proteins. Ask your doctor if you are not sure.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and eye drops, vitamins, and herbal supplements. Some of your other medicines or supplements may affect the way tiotropium bromide inhalation powder works. Tiotropium bromide inhalation powder is an anticholinergic medicine. You should not take other anticholinergic medicines while using tiotropium bromide inhalation powder, including ipratropium. Ask your doctor or pharmacist if you are not sure if one of your medicines is an anticholinergic.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

How should I take tiotropium bromide inhalation powder?

- Use tiotropium bromide inhalation powder exactly as prescribed. Use tiotropium bromide inhalation powder one time every day.
- Read the “Instructions for Use” at the end of this leaflet before you use tiotropium bromide inhalation powder. Talk with your doctor if you do not understand the instructions.
- **Do not swallow tiotropium bromide inhalation powder capsules.**
- **Only use tiotropium bromide inhalation powder capsules with the LupinHaler device.**
- **Do not use the LupinHaler device to take any other medicine.**
- Tiotropium bromide inhalation powder comes as a powder in a tiotropium bromide inhalation powder capsule that fits the LupinHaler device. Each tiotropium bromide inhalation powder capsule, containing only a small amount of tiotropium bromide inhalation powder, is one full dose of medicine.
- Separate one blister from the blister card. Then take out one of the tiotropium bromide inhalation powder capsules from the blister package right before you use it.
- After the capsule is pierced, take a complete dose of tiotropium bromide inhalation powder by breathing in the powder by mouth two times, using the LupinHaler device (take 2 inhalations from one tiotropium bromide inhalation powder capsule). See the “**Instructions for Use**” at the end of this leaflet.
- Throw away any tiotropium bromide inhalation powder capsule that is not used right away after it is taken out of the blister package. Do not leave the tiotropium bromide inhalation powder capsules open to air; they may not work as well.
- If you miss a dose, take it as soon as you remember. Do not use tiotropium bromide inhalation powder more than one time every 24 hours.
- If you use more than your prescribed dose of tiotropium bromide inhalation powder, call your doctor or a poison control center.

What should I avoid while using tiotropium bromide inhalation powder?

- 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.

What are the possible side effects of tiotropium bromide inhalation powder?

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

If you have these symptoms of an allergic reaction, stop taking tiotropium bromide inhalation powder and call your doctor right away or go to the nearest hospital emergency room.

- **Sudden narrowing and blockage of the airways into the lungs (bronchospasm).** Your breathing suddenly gets worse.

If you have these symptoms of bronchospasm, stop taking tiotropium bromide inhalation powder and call your doctor right away or go to the nearest hospital emergency room.

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 eyes

Using only eye drops to treat these symptoms may not work. If you have these symptoms, stop taking tiotropium bromide inhalation powder and call your doctor right away.

- **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 these symptoms of urinary retention, stop taking tiotropium bromide inhalation powder and call your doctor right away.

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

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 may report side effects to FDA at 1-800-FDA-1088.

How do I store tiotropium bromide inhalation powder?

- **Do not store tiotropium bromide inhalation powder capsules in the LupinHaler device.**

- Store tiotropium bromide inhalation powder capsules in the sealed blister package at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep tiotropium bromide inhalation powder capsules away from heat and cold (do not freeze).
- Store tiotropium bromide inhalation powder capsules in a dry place. Throw away any unused tiotropium bromide inhalation powder capsules that have been open to air.

Ask your doctor or pharmacist if you have any questions about storing your tiotropium bromide inhalation powder capsules.

Keep LupinHaler, tiotropium bromide inhalation powder capsules, and all medicines out of the reach of children.

General information about tiotropium bromide inhalation powder

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use tiotropium bromide inhalation powder for a purpose for which it has not been prescribed. Do not give tiotropium bromide inhalation powder to other people even if they have the same symptoms that you have. It may harm them.

For more information about tiotropium bromide inhalation powder, talk with your doctor. You can ask your doctor or pharmacist for information about tiotropium bromide inhalation powder that is written for health professionals.

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.

What are the ingredients in tiotropium bromide inhalation powder?

Active ingredient: tiotropium

Inactive ingredient: lactose monohydrate

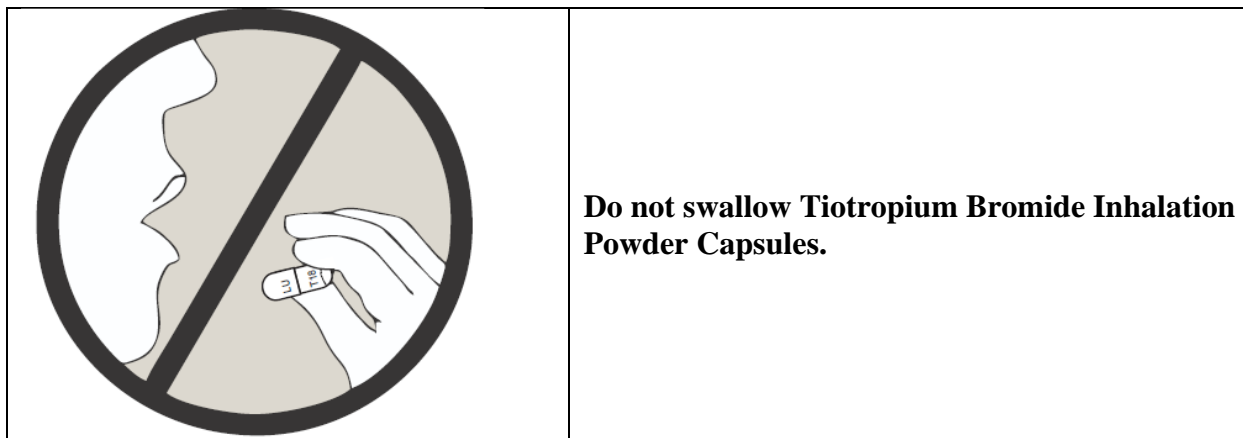
What is COPD (Chronic Obstructive Pulmonary Disease)?

COPD is a serious lung disease that includes chronic bronchitis, emphysema, or both. Most COPD is caused by smoking. When you have COPD, your airways become narrow. So, air moves out of your lungs more slowly. This makes it hard to breathe.

This Patient Information has been approved by the U.S. Food and Drug Administration.

INSTRUCTIONS FOR USE

Tiotropium Bromide (tye-oh-TROE-pee-um BROE-mide) Inhalation Powder LupinHaler™



Important Information about using your tiotropium bromide inhalation powder LupinHaler

- **Do not swallow tiotropium bromide inhalation powder capsules.**
- **Tiotropium bromide inhalation powder capsules should only be used with the LupinHaler device and inhaled through your mouth (oral inhalation).**
- **Do not use your LupinHaler device to take any other medicine.**

First read the Patient Information, then read these Instructions for Use before you start to use tiotropium bromide inhalation powder LupinHaler and each time you refill your prescription. There may be new information.

Becoming familiar with your LupinHaler device and tiotropium bromide inhalation powder capsules:

Your tiotropium bromide inhalation powder comes with tiotropium bromide inhalation powder capsules in blister packaging and a LupinHaler device. Use the new LupinHaler device provided with your medicine.

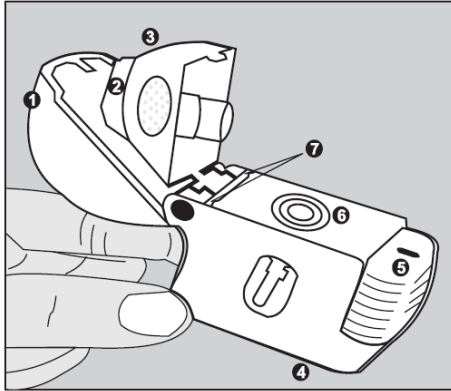


Figure A

The parts of your LupinHaler device include:

(See Figure A)

1. dust cap (lid)
2. mouthpiece
3. mouthpiece ridge
4. base
5. green piercing button
6. center chamber
7. air intake vents



Figure B

Each tiotropium bromide inhalation powder capsule is packaged in a blister. (See Figure B)

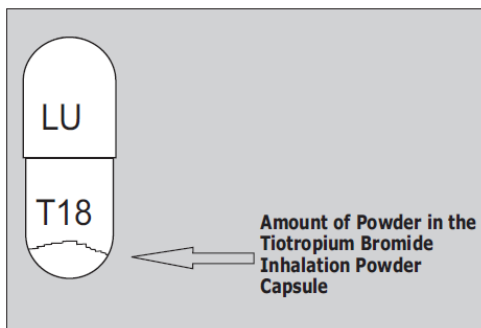


Figure C

- Each tiotropium bromide inhalation powder capsule contains only a small amount of powder. (See Figure C) This is 1 full dose.
- **Do not open the tiotropium bromide inhalation powder capsule or it may not work.**

Taking your full daily dose of medicine requires 4 main steps.

Step 1. Opening your LupinHaler device:

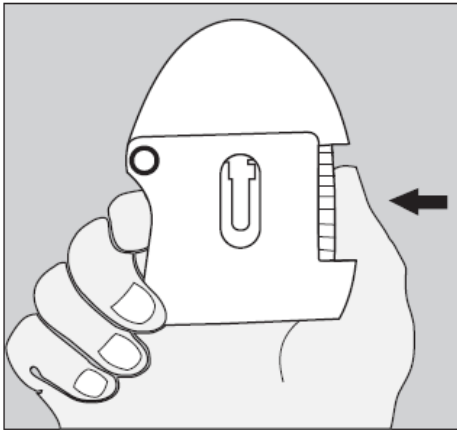


Figure D

After removing your LupinHaler device from the pouch:

- Open the dust cap (lid) by pressing the green piercing button. (See Figure D)

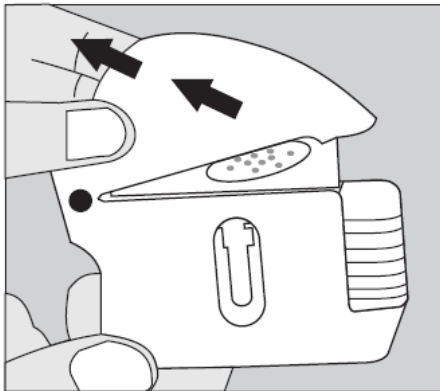


Figure E

- Pull the dust cap (lid) upwards away from the base to expose the mouthpiece. (See Figure E)

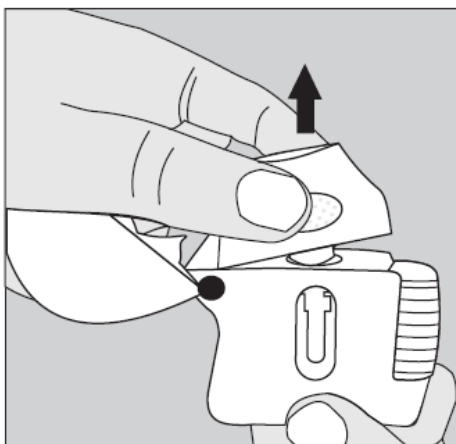


Figure F

- Open the mouthpiece by pulling the mouthpiece ridge up and away from the base so the center chamber is showing. (See Figure F)

Step 2. Inserting the tiotropium bromide inhalation powder capsule into your LupinHaler device:

Each day, separate only 1 of the blisters from the blister card by tearing along the perforated line. (See Figure G)

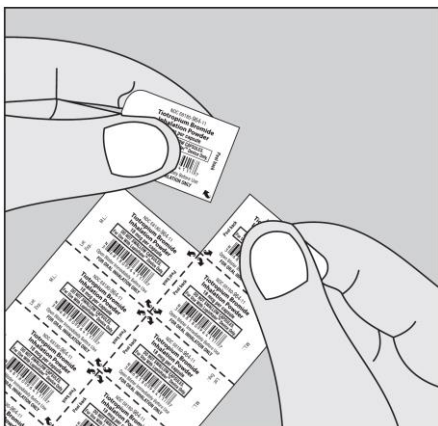


Figure G



Figure H

Remove the tiotropium bromide inhalation powder capsule from the blister:

- **Do not** cut the foil or use sharp instruments to take out the tiotropium bromide inhalation powder capsule from the blister.
- Bend 1 of the blister corners with an arrow and separate the aluminum foil layers.
- Peel back the printed foil until you see the whole tiotropium bromide inhalation powder capsule. (See Figure H)
- If you have opened more than 1 blister to the air, the extra tiotropium bromide inhalation powder capsule should not be used and should be thrown away.

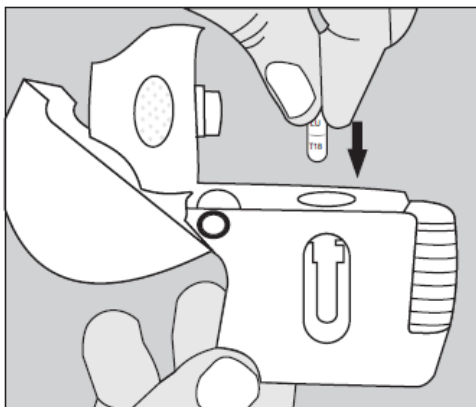


Figure I

Place the tiotropium bromide inhalation powder capsule in the center chamber of your LupinHaler device. (See Figure I)

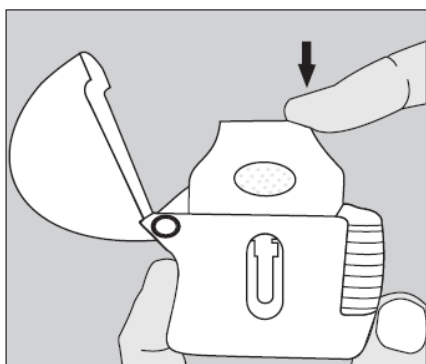


Figure J

Close the mouthpiece firmly against the white base until you hear a click. Leave the dust cap (lid) open. (See Figure J)

Step 3. Piercing the tiotropium bromide inhalation powder capsule:

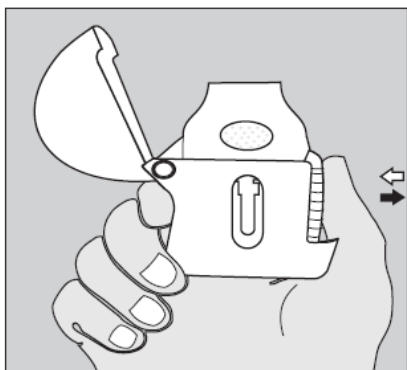


Figure K

- Hold your LupinHaler device with the mouthpiece pointed up. (See Figure K)
- Press the green piercing button once until it is flat (flush) against the base, then release. This is how you make holes in the tiotropium bromide inhalation powder capsule so that you get your medicine when you breathe in.
- **Do not** press the green button more than one time.
- **Do not** shake your LupinHaler device.
- The piercing of the tiotropium bromide inhalation powder capsule may produce small pieces of the capsule. Some of these small pieces may pass through the screen of your LupinHaler device into your mouth or throat when you breathe in your medicine. This is normal. The small pieces of the capsule should not harm you.

Step 4. Taking your full daily dose (2 inhalations from the same tiotropium bromide inhalation powder capsule):

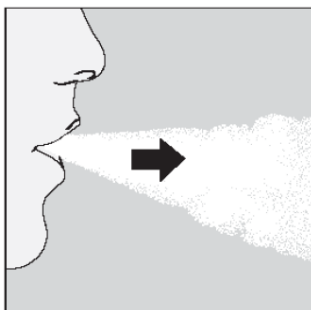


Figure L

Breathe out completely in 1 breath, emptying your lungs of any air. (See Figure L)

Important: Do not breathe into your LupinHaler device.

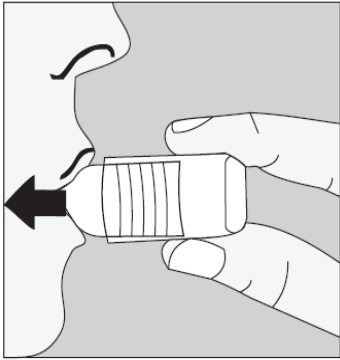


Figure M

With your next breath, take your medicine:

- **Hold your head in an upright position while you are looking straight ahead.** (See Figure M)
- Raise your LupinHaler device 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. You should **hear or feel the tiotropium bromide inhalation powder capsule vibrate (rattle)**. (See Figure M)
- Hold your breath for a few seconds and, at the same time, take your LupinHaler device out of your mouth.
- Breathe normally again.

The rattle tells you that you breathed in correctly. If you do not hear or feel a rattle, see the section, “If you do not hear or feel the tiotropium bromide inhalation powder capsule rattle as you breathe in your medicine.”

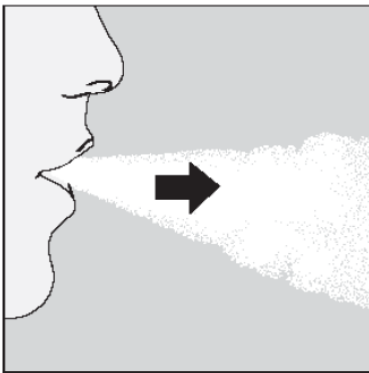


Figure N

To get your full daily dose, you must again, breathe out completely (See Figure N) and for a second time, breathe in (See Figure O) from the same tiotropium bromide inhalation powder capsule.

Important: Do not press the green piercing button again.

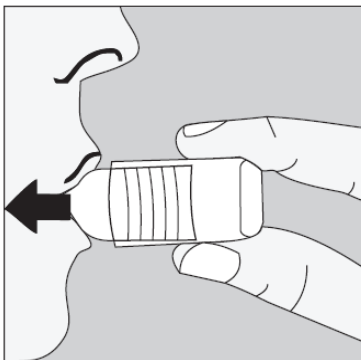


Figure O

Remember: To get your full medicine dose each day, you must breathe in 2 times from the same tiotropium bromide inhalation powder capsule. Make sure you breathe out completely each time before you breathe in from your LupinHaler device.

Caring for and storing your tiotropium bromide inhalation powder LupinHaler:

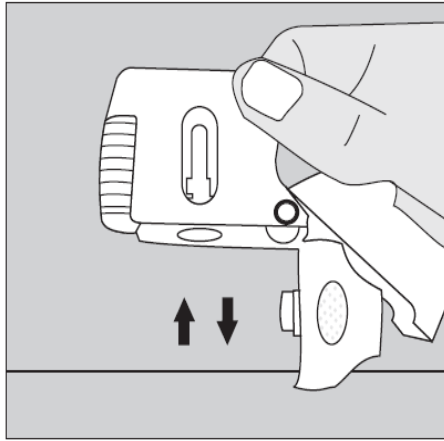


Figure P

- After taking your daily dose, open the mouthpiece and tip out the used tiotropium bromide inhalation powder capsule into your trash can, without touching it.
- Remove any tiotropium bromide inhalation powder capsule pieces or tiotropium bromide inhalation powder buildup by turning your LupinHaler device upside down and gently, but firmly, tapping it. (See Figure P) Then, close the mouthpiece and dustcap for storage.
- **Do not** store your LupinHaler device and tiotropium bromide inhalation powder capsules (blisters) in a damp moist place. Always store tiotropium bromide inhalation powder capsules in the sealed blisters.

If you do not hear or feel the tiotropium bromide inhalation powder capsule rattle as you breathe in your medicine:

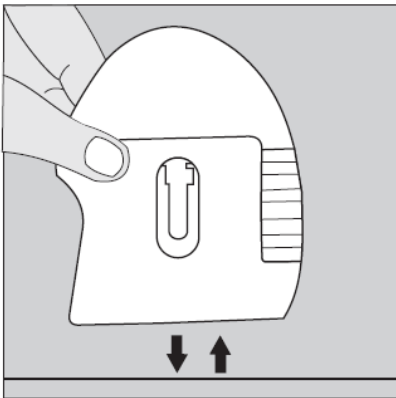


Figure Q

Do not press the green piercing button again.

Hold your LupinHaler device with the mouthpiece pointed up and tap your LupinHaler device gently on a table. (See Figure Q)

Check to see that the mouthpiece is completely closed. Breathe out completely before deeply breathing in again with the mouthpiece in your mouth. (See Figure O)

If you still do not hear or feel the tiotropium bromide inhalation powder capsule rattle after repeating the above steps:

- Throw away the tiotropium bromide inhalation powder capsule.
- Open the base by lifting the green piercing button and check the center chamber for pieces of the tiotropium bromide inhalation powder capsule. Tiotropium bromide inhalation powder capsule pieces in the center chamber can cause a tiotropium bromide inhalation powder capsule not to rattle.
- Turn your LupinHaler device upside down and gently, but firmly, tap to remove the tiotropium bromide inhalation powder capsule pieces. Call your doctor for instructions.

Cleaning your LupinHaler device:

Clean your LupinHaler device as needed. (See Figure R)

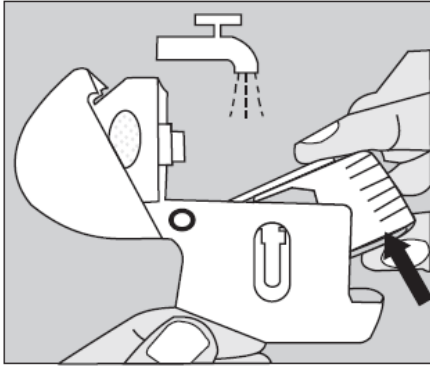


Figure R

- **It takes 24 hours to air dry your LupinHaler device** after you clean it.
- **Do not** use cleaning agents or detergents.
- **Do not** place your LupinHaler device in the dishwasher for cleaning.

Cleaning Steps:

- Open the dust cap and mouthpiece
- Open the base by lifting the green piercing button.
- Look in the center chamber for tiotropium bromide inhalation powder capsule pieces or powder buildup. If seen, tap out.
- Rinse your LupinHaler device with warm water, pressing the green piercing button a few times so that the center chamber and the piercing needle is under the running water. Check that any powder buildup or tiotropium bromide inhalation powder capsule pieces are removed.
- Dry your LupinHaler device well by tipping the excess water out on a paper towel. Air-dry afterwards, leaving the dust cap, mouthpiece, and base open by fully spreading it out so that it dries completely.
- **Do not** use a hair dryer to dry your LupinHaler device.
- **Do not** use your LupinHaler device when it is wet. If needed, you may clean the outside of the mouthpiece with a clean damp cloth.

Helpful Hints to help ensure that you are properly taking your full daily dose of tiotropium bromide inhalation powder LupinHaler:

- **Press** the green piercing button **1 time**; **Breathe in 2 times**; **Breathe out completely** before each of the **2** inhalations.
- Always use the new LupinHaler device provided with your medicine.
- Keep your LupinHaler device with the mouthpiece pointed up when pressing the green piercing button.
- **Press the green piercing button 1 time** to pierce the tiotropium bromide inhalation powder capsule.
- Do not breathe out into your LupinHaler device.
- Keep your LupinHaler device in a horizontal position and keep your head upright, looking straight ahead, when breathing in.
- Check the center chamber of your LupinHaler device for tiotropium bromide inhalation powder capsule pieces or powder build-up. If pieces or powder are seen, tap out before use.
- Clean your LupinHaler as needed and dry thoroughly.

For more information, ask your doctor or pharmacist, or visit our website at www.lupinpharmaceuticals.com, or contact Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

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

LupinHaler™ is a trademark of Lupin Pharmaceuticals, Inc.

®The brands listed are trademarks of their respective owners and are not trademarks of Lupin Pharmaceuticals, Inc. The makers of these brands are not affiliated with and do not endorse Lupin Pharmaceuticals, Inc. or its products.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

India

September 2022