

Tiotropium Lupin

Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Tiotropium Lupin?

Tiotropium Lupin capsules contain the active ingredient tiotropium. Tiotropium Lupin is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD)

For more information, see Section [1. Why am I using Tiotropium Lupin?](#) in the full CMI.

2. What should I know before I use Tiotropium Lupin?

Do not use if you have ever had an allergic reaction to tiotropium, atropine, medicines like atropine (eg. ipratropium or oxitropium) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Tiotropium Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tiotropium Lupin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Tiotropium Lupin?

- The recommended dose for adults is 1 capsule to be inhaled, once a day.
- Use the LupinHaler device to inhale the powder in the capsules.
- Do not swallow the capsules.

More instructions can be found in Section [4. How do I use Tiotropium Lupin?](#) in the full CMI.

5. What should I know while using Tiotropium Lupin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Tiotropium Lupin.• Tell your doctor immediately if your breathing becomes more difficult while you are taking Tiotropium Lupin.
Things you should not do	<ul style="list-style-type: none">• Do not use Tiotropium Lupin more frequently than once daily.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Tiotropium Lupin affects you.• Tiotropium Lupin may cause dizziness or blurred vision in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in a cool, dry place where the temperature stays below 25°C. Do not store your capsules in the freezer.• Keep your capsules in the pack until it is time to take them.

For more information, see Section [5. What should I know while using Tiotropium Lupin?](#) in the full CMI.

6. Are there any side effects?

A common side effect is dry mouth, which is usually mild.

Side effects that require urgent medical attention include allergic reaction, changes in heart rate or palpitations and severe pain in the stomach with bloating, gut cramps and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Tiotropium Lupin

Active ingredient(s): *tiotropium (as tiotropium bromide monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tiotropium Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tiotropium Lupin.**

Where to find information in this leaflet:

- [1. Why am I using Tiotropium Lupin?](#)
- [2. What should I know before I use Tiotropium Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Tiotropium Lupin?](#)
- [5. What should I know while using Tiotropium Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Tiotropium Lupin?

Tiotropium Lupin contains the active ingredient **tiotropium**. It belongs to a group of medicines called anticholinergics.

Tiotropium Lupin is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD).

This helps to improve your condition and to prevent exacerbations (periodic worsening of symptoms) from occurring.

Tiotropium Lupin improves breathing by relaxing the air passages that carry air to and from the lungs. It begins to act within 30 minutes after use and the effect should last a full day.

2. What should I know before I use Tiotropium Lupin?

Warnings

Do not use Tiotropium Lupin to treat a sudden attack of breathlessness, wheezing or coughing. You will need a different type of medicine.

Do not use Tiotropium Lupin if:

- you are allergic to tiotropium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to atropine or substances related to it, eg. ipratropium or oxitropium.

- you have been told by your doctor that you have an intolerance to some sugars, or an allergy to milk proteins (which may be contained in small amounts in the ingredient lactose monohydrate).

Check with your doctor if you:

- you have or have had any of the following medical conditions:
 - high pressure in the eye (glaucoma);
 - kidney or liver problems;
 - problems with your prostate gland;
 - problems with passing urine.
- you have suffered from a heart attack during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved. Tiotropium Lupin is not generally recommended for use in pregnant women.

Children and adolescents

Do not give this medicine to children or adolescents (below the age of 18 years).

Eyes

Do not allow the powder to enter into the eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes and immediately consult your doctor for further advice.

If the powder enters the eye, it may result in eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes (ie. narrow angle glaucoma).

Device

Use this medicine only with the LupinHaler device.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Tiotropium Lupin may interfere with each other. These include:

- other anticholinergic medicines used to treat COPD, such as glycopyrronium, aclidinium, umeclidinium or ipratropium.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tiotropium Lupin.

4. How do I use Tiotropium Lupin?

How much to use

- The recommended dose for adults is 1 capsule to be inhaled, once a day.
- Follow the instructions provided and use Tiotropium Lupin until your doctor tells you to stop.

When to use Tiotropium Lupin

- Tiotropium Lupin should be used at about the same time each day.

How to use Tiotropium Lupin (

- Inhale the powder in the capsules only using the LupinHaler device.
- Do not swallow the capsules.
- Do not open the capsules. If you open the capsules, the small amount of powder inside may be lost, or you may accidentally get the powder in your eyes.
- Read the LupinHaler Instructions for Use at the end of this CMI for instructions on how to use Tiotropium Lupin capsules with the LupinHaler device. These instructions are also available in a leaflet supplied with the product.
- Pierce the capsule only once using the LupinHaler device. If you pierce it more than once, the capsule may break and pieces of gelatin from the capsule shell, small enough to pass the sieve, may be inhaled into your mouth or throat. Gelatin is not harmful and small particles swallowed or inhaled will be digested or absorbed and are not expected to cause undesirable effects.
- Do not allow the powder to enter into the eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.
- If you have any problems inhaling Tiotropium Lupin using the LupinHaler device, ask your doctor or pharmacist for advice.

If you forget to use Tiotropium Lupin

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Tiotropium Lupin

If you think that you have used too much Tiotropium Lupin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include fast or irregular heartbeat, blurred vision, nausea, stomach pain, dry mouth, constipation and difficulty passing urine.

5. What should I know while using Tiotropium Lupin?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Tiotropium Lupin, especially if you are about to start any new medicine or if you are going to have surgery.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- It is very important to follow the LupinHaler Instructions for Use carefully.
- If you are a smoker, your doctor or pharmacist can advise you on the steps to take to quit smoking.

Tell your doctor immediately if:

- you become pregnant while using Tiotropium Lupin.
- your breathing becomes more difficult while you are using Tiotropium Lupin.

Things you should not do

- Do not use Tiotropium Lupin to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use Tiotropium Lupin more frequently than once daily.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tiotropium Lupin affects you.

Tiotropium Lupin may cause dizziness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Looking after your medicine

- Refer to the LupinHaler Instructions for Use on how to clean and take care of your LupinHaler.
- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.
- Keep your capsules in a place where the temperature stays below 25°C. Do not store your capsules in the freezer

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Brain and nerves:</p> <ul style="list-style-type: none"> • Dizziness. • Trouble sleeping. <p>Nose and sinus:</p> <ul style="list-style-type: none"> • Nose bleeds. • Sinusitis, a feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>Mouth, throat and airways:</p> <ul style="list-style-type: none"> • Dry mouth: this is usually mild. • Sore mouth, gums, or throat. • Swollen, red, sore tongue. • Oral thrush. • Hoarse voice. • Cough. <p>Gut and digestion:</p> <ul style="list-style-type: none"> • Constipation. 	
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Serious side effects

Serious side effects	What to do
<p>Eyes:</p> <ul style="list-style-type: none"> • Blurred vision. • Seeing halos around lights or coloured images in association with red eyes. • High pressure in the eye (glaucoma). <p>Mouth, throat and airways:</p> <ul style="list-style-type: none"> • Difficulty in swallowing. • Worsening of breathing problems (induced by the inhalation process). Inhaled medicines such as Tiotropium Lupin may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation. <p>Gut and digestion:</p> <ul style="list-style-type: none"> • Heartburn. <p>Bladder:</p> <ul style="list-style-type: none"> • Difficulty in passing urine. • Pain while passing urine, urinary tract infection, increased need and frequency in passing urine. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • Shortness of breath, wheezing or difficulty breathing. • Swelling of the face, lips, tongue or other parts of the body. • Rash, itching or hives on the skin. <p>Heart:</p> <ul style="list-style-type: none"> • Changes in heart rate (fast, slow or irregular). • Palpitations. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

<p>Gut and digestion:</p> <ul style="list-style-type: none"> • Severe pain in the stomach with bloating, gut cramps and vomiting. 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Tiotropium Lupin contains

Active ingredient (main ingredient)	Tiotropium (as tiotropium bromide monohydrate)
Other ingredients (inactive ingredients)	Lactose monohydrate

Potential allergens	Lactose
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Do not take this medicine if you are allergic to any of these ingredients.

What Tiotropium Lupin looks like

Tiotropium Lupin capsules are opaque white in colour, imprinted with "LU" on cap and "T18" on body with black ink. The capsules contain a white powder (AUST R 393051).

Tiotropium Lupin is available in cartons containing combination pack of 30 capsules and the LupinHaler device.

Who distributes Tiotropium Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

✉ ghinfo@generichealth.com.au

☎ +61 3 9809 7900

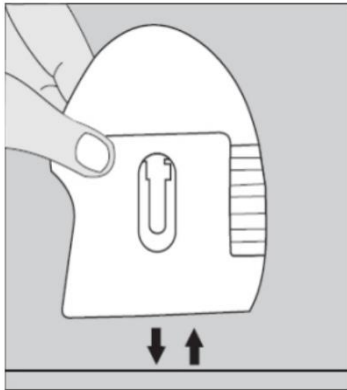
🌐 www.generichealth.com.au

This leaflet was prepared in June 2023.

LUPINHALER INSTRUCTIONS FOR USE

The LupinHaler (refer Figure 1) enables you to inhale the medicine contained in the capsule that your physician has prescribed for your breathing problems.

Figure 1



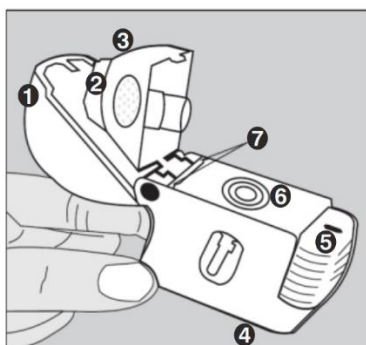
Remember to carefully follow your doctor's instructions for using Tiotropium Lupin 18 microgram, inhalation powder. The LupinHaler is especially designed for the Tiotropium Lupin, capsule which contains the inhalation powder. You must not use the LupinHaler to take any other medication. You can use your LupinHaler until you have finished the medicine contained in this box.

LupinHaler Components

The LupinHaler is made of the following components (refer Figure 2):

1. Dust cap (lid).
2. Mouthpiece.
3. Mouthpiece grip.
4. Base.
5. Green Piercing button.
6. Centre chamber.
7. Air Intake vents.

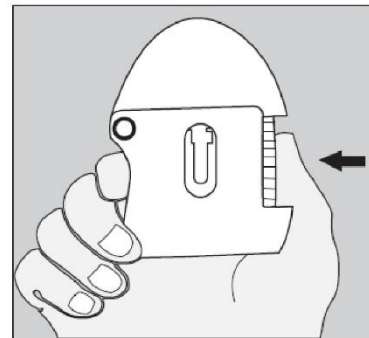
Figure 2



How to use the LupinHaler

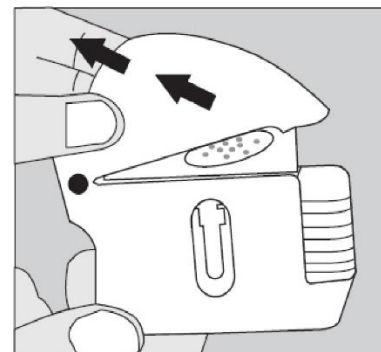
1. After removing LupinHaler device from the pouch, open the dust cap (lid) by pressing the green piercing button (refer Figure 3).

Figure 3



2. Pull the dust cap (lid) upwards away from the base to expose the mouthpiece. Open the mouthpiece by pulling the mouthpiece ridge up and away from the base so the centre chamber is showing. Then open the mouthpiece by pulling it upwards (refer Figure 4).

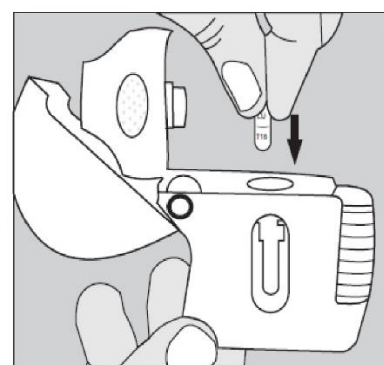
Figure 4



3. Remove a Tiotropium Lupin 18 microgram, inhalation powder capsule from the blister (only immediately before use, see Blister Handling below).

Place the capsule in the centre chamber as illustrated (refer Figure 5). It does not matter which way the capsule is placed in the chamber.

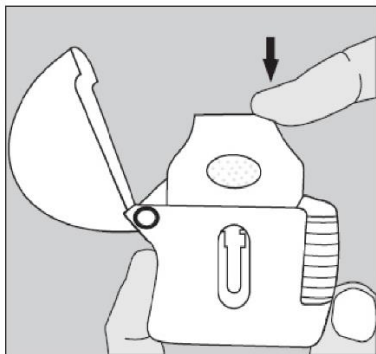
Figure 5



4. Close the mouthpiece firmly against the transparent base until you hear a click (refer Figure 6).

Leave the dust cap (lid) open.

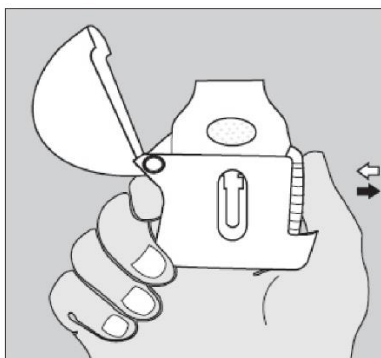
Figure 6



5. Hold the LupinHaler device with the mouthpiece upwards and press the piercing button completely in only once, and release (refer Figure 7).

This makes holes in the capsule and allows the medication to be released when you breathe in.

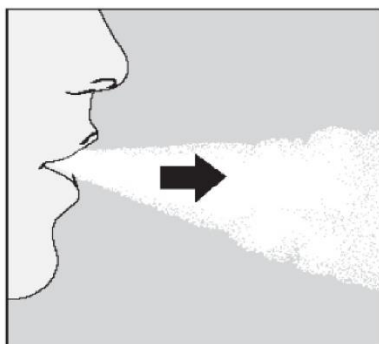
Figure 7



6. Breathe out completely (refer Figure 8).

Important: Please avoid breathing into the mouthpiece at any time.

Figure 8

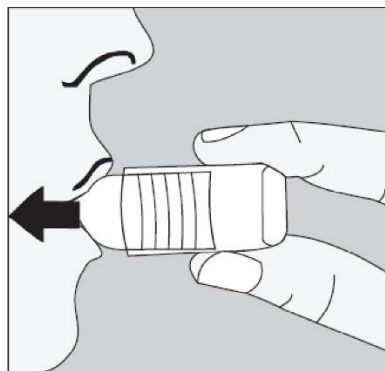


7. Raise the LupinHaler to your mouth and close your lips tightly around the mouthpiece (refer Figure 9). Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate.

Breathe in until your lungs are full; then hold your breath as long as comfortable and at the same time take the LupinHaler out of your mouth. Resume normal breathing.

Repeat steps 6 and 7 once, in order to empty the capsule completely.

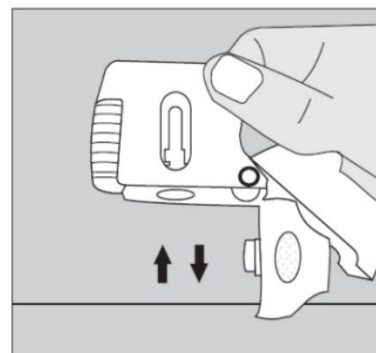
Figure 9



8. Open the mouthpiece again. Tip out the used capsule and dispose of it appropriately (refer Figure 10). As the empty capsule may still contain some powder, it should be disposed of carefully.

Close the mouthpiece and dust cap for storage of your LupinHaler device.

Figure 10



Cleaning your LupinHaler

Clean the LupinHaler once a month (refer Figure 11).

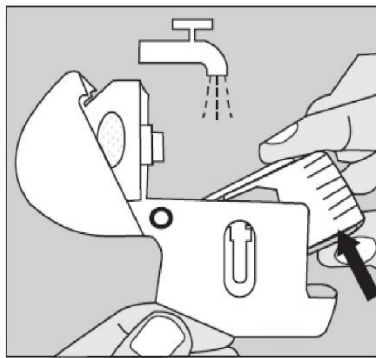
Open the dust cap and mouthpiece, then open the base by lifting the piercing button.

Rinse all components of the LupinHaler completely with warm water to remove any powder.

Dry the LupinHaler thoroughly by tipping any excess water out on a paper towel and allowing the LupinHaler to air dry afterwards, leaving the dust cap, mouthpiece and base open.

It takes 24 hours to air dry, so clean it right after you have used it and it will be ready for your next dose. If needed, the outside of the mouthpiece may be cleaned with a moist but not wet tissue.

Figure 11



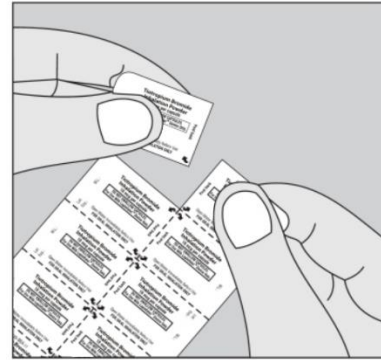
Blister Handling

Tiotropium Lupin inhalation power capsules contain only a small amount of powder so that the capsule is only partially filled.

Follow the instructions below on how to remove a capsule from the blister.

1. Separate the blister strips by tearing along the perforation (refer Figure 12).

Figure 12



2. Only immediately before using the capsule, peel back foil at the "peel back" area indicated on the blister until one capsule is fully visible.

Remove capsule from blister pocket (refer Figure 13).

If another capsule is exposed to air inadvertently during this process, that capsule has to be discarded.

Figure 13



The LupinHaler is a Medical Device (CE).

The manufacturer for the LupinHaler device is:

RPC Formatec

Stockheimer Strasse 30

97638 Mellrichstadt

Germany

Who distributes Tiotropium Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

✉ ghinfo@generichealth.com.au

☎ +61 3 9809 7900

🌐 www.generichealth.com.au