

TRELEGY ELLIPTA 100/62.5/25 and 200/62.5/25

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 TRELEGY ELLIPTA?

TRELEGY ELLIPTA contains the active ingredients fluticasone furoate, umeclidinium (as bromide) and vilanterol (as trifenate). TRELEGY ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD).

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

2. What should I know before I use TRELEGY ELLIPTA?

Do not use if you have ever had an allergic reaction to TRELEGY ELLIPTA 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 TRELEGY ELLIPTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRELEGY ELLIPTA 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 TRELEGY ELLIPTA?

- The usual dose of TRELEGY ELLIPTA for asthma and COPD is one inhalation 100 micrograms of fluticasone furoate, 62.5 micrograms umeclidinium and 25 micrograms of vilanterol once daily, at the same time each day.
- If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength TRELEGY ELLIPTA (200 micrograms of fluticasone furoate, 62.5 micrograms of umeclidinium and 25 micrograms of vilanterol).

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

5. What should I know while using TRELEGY ELLIPTA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using TRELEGY ELLIPTA.• Contact your doctor if you are concerned about any side effects.• Tell your doctor immediately if you become pregnant while using TRELEGY ELLIPTA.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.• Do not use TRELEGY ELLIPTA 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 take any other medicines for your breathing problems without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Take caution while driving or operating machinery until you know how TRELEGY ELLIPTA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store in the original package container to protect from moisture and do not open the foil lid until ready to inhale.• Keep your inhaler in a cool dry place where the temperature stays below 30°C. If you store in a refrigerator allow the inhaler to return to room temperature for at least an hour before use.

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

6. Are there any side effects?

Less serious side effects include headache, changes in taste, tremor, oral fungal infection, infection of the upper airways, influenza, common cold, cough, hoarseness, itchy, runny or blocked nose or pain in the back of the mouth and throat. Serious side effects include pneumonia, bronchitis, inflammation of the sinuses, infection of the nose, sinuses or throat, immediate breathing difficulties and wheezing, allergic reaction, osteoporosis, hyperglycaemia, painful and frequent urination, urinary retention, dysuria, irregular heartbeat, faster heartbeat, palpitations, blurred vision, increased eye pressure or eye pain.

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.

TRELEGY ELLIPTA

Active ingredient(s): fluticasone furoate 100 or 200 micrograms, umeclidinium (as bromide) 62.5 micrograms and vilanterol (as trifenate) 25 micrograms per inhalation

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRELEGY ELLIPTA. **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 TRELEGY ELLIPTA.**

Where to find information in this leaflet:

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

1. Why am I using TRELEGY ELLIPTA?

TRELEGY ELLIPTA contains the active ingredients fluticasone furoate, umeclidinium (as bromide) and vilanterol (as trifenate). Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Umeclidinium and vilanterol belong to a group of medicines called bronchodilators.

TRELEGY ELLIPTA is used to treat asthma and chronic obstructive pulmonary disease (COPD).

Asthma is when the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen, and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

COPD is a long-term condition that slowly gets worse. Symptoms include shortness of breath, cough, chest discomfort and coughing up mucous.

Corticosteroids are used to reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Bronchodilators relax the muscles of the small air passages in the lungs. This helps to open the airways and make it easier for air to get in and out of the lungs. When it is taken regularly, it helps the small air passages to remain open.

When TRELEGY ELLIPTA is used regularly, it can help to control your breathing difficulties.

TRELEGY ELLIPTA should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting inhaler (such as VENTOLIN).

Your doctor may have prescribed TRELEGY ELLIPTA for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

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

TRELEGY ELLIPTA should not be used in children or adolescents under the age of 18 years.

2. What should I know before I use TRELEGY ELLIPTA?

Warnings

Do not use TRELEGY ELLIPTA if:

- you are allergic (hypersensitive) to fluticasone furoate, umeclidinium, vilanterol, or any of the ingredients listed at the end of this leaflet.
- you are allergic (hypersensitive) to lactose or milk protein.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have been diagnosed with an intolerance to some sugars, or to milk protein.
- have liver disease, as you may be more likely to have side effects. If you have moderate or severe liver disease, your doctor will limit your dose to the lower strength of TRELEGY ELLIPTA (100/62.5/25 micrograms once daily).
- have heart problems or high blood pressure.
- have been told you have diabetes or high blood sugar.
- are being or have been treated for tuberculosis (TB) or pneumonia.
- have weak bones (osteoporosis).
- have eye problems such as glaucoma or cataracts.
- have an enlarged prostate, difficulty passing urine or a blockage in your bladder.
- have any type of viral, bacterial, or fungal infection.
- have a problem with your immune system.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

TRELEGY ELLIPTA is not usually recommended for use during pregnancy.

Your doctor will consider the benefit to you and the risk to your baby of taking TRELEGY ELLIPTA while you are pregnant.

It is not known whether the ingredients of TRELEGY ELLIPTA can pass into breast milk.

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 may interfere with TRELEGY ELLIPTA and affect how it works or make it more likely that you will have side effects.

These medicines include:

- ketoconazole, to treat fungal infections.
- ritonavir, to treat HIV.
- other long-acting medicines similar to this medicine that are used to treat breathing problems (i.e. inhalers used as maintenance or preventer therapy).
- medicines to treat depression or mood/mental disorders (such as monoamine oxidase inhibitors or tricyclic antidepressants).

Medicines that should be avoided:

- A class of medicines called beta blockers, used to treat high blood pressure or other heart problems.

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

4. How do I use TRELEGY ELLIPTA?

How much to use

Always use TRELEGY ELLIPTA exactly as your doctor has told you. Check with your doctor, nurse, or pharmacist if you are not sure.

Asthma:

- The dose for asthma is one inhalation of TRELEGY ELLIPTA 100/62.5/25 micrograms once daily, at the same time each day OR one inhalation of TRELEGY ELLIPTA 200/62.5/25 micrograms once daily, at the same time each day.
- Your doctor will decide which strength of TRELEGY ELLIPTA is required to treat your asthma.

COPD:

- The dose for COPD is one inhalation of TRELEGY ELLIPTA 100/62.5/25 micrograms once daily, at the same time each day.

When to use TRELEGY ELLIPTA

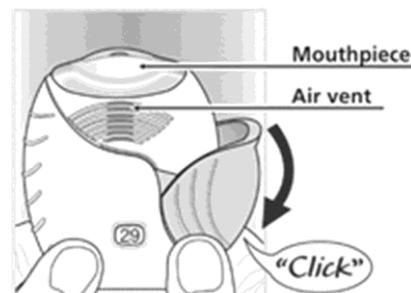
- Use TRELEGY ELLIPTA regularly.
- It is very important that you use TRELEGY ELLIPTA every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.
- Use TRELEGY ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.

How to use TRELEGY ELLIPTA

- To use TRELEGY ELLIPTA, you breathe it into your lungs through your mouth using the Ellipta inhaler.
- TRELEGY ELLIPTA is a dry powder inhaler. When you breathe in using the inhaler, the medicine is deposited into the lungs.
- The full instructions for using TRELEGY ELLIPTA are given on a leaflet inside the pack. A brief summary of the instructions is provided below.
- TRELEGY ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.
- Do not open TRELEGY ELLIPTA until you are ready to inhale a dose of medicine.

Step 1: Prepare a dose

- Wait to open the cover until you are ready to take your dose. Slide the cover fully down until you hear a "click".
- If the dose counter does not count down as you hear the "click", the inhaler will not deliver medicine. Take it back to your pharmacist for advice.
- Do not shake the inhaler at any time.



Step 2: Inhale your medication

- While holding the inhaler away from your mouth, breathe out as far as is comfortable.
- Do not breathe out into the inhaler.
- Put the mouthpiece between your lips and close your lips firmly around it.
- Do not block the air vent with your fingers.



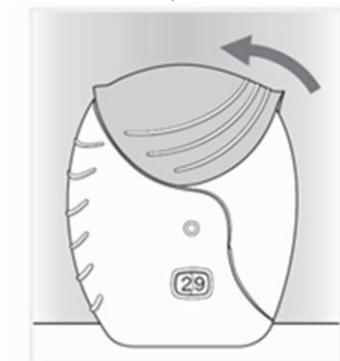
- Take one long, steady, deep breath in. Hold this breath for about 3-4 seconds or as long as is comfortable.
- Remove the inhaler from your mouth.
- Breathe out slowly and gently away from the mouthpiece.
- You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

After using TRELEGY ELLIPTA, you may clean the mouthpiece, using a dry tissue, before you close the cover.

Do not immerse TRELEGY ELLIPTA in water.

Step 3: Close the inhaler and rinse your mouth

- Slide the cover upwards as far as it will go, to cover the mouthpiece.



- Rinse your mouth out with water without swallowing after you have used the inhaler. This will make it less likely that you will develop a sore mouth or throat as side effects.

If you forget to use TRELEGY ELLIPTA

TRELEGY ELLIPTA should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, then go back to using it as you would normally.

Do not use an extra dose to make up for the dose you missed.

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, use your quick-acting inhaler (e.g. VENTOLIN), then seek medical advice.

If you use too much TRELEGY ELLIPTA (overdose)

If you think that you have used too much TRELEGY ELLIPTA, you may need urgent medical attention. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766**), 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.

If you have used larger doses than instructed for a long period of time, it is particularly important that you ask your doctor or pharmacist for advice. This is because larger doses of TRELEGY ELLIPTA may reduce the amount of steroid hormones produced naturally by your body.

5. What should I know while using TRELEGY?

Things you should do

- Remind any doctor, dentist, or pharmacist you visit that you are using TRELEGY ELLIPTA, especially if you are about to be started on any new medicine.
- Use TRELEGY ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- experience blurred vision or other visual disturbances.
- experience increased thirst, frequent urination, or unexplained tiredness (signs of high blood sugar).
- become pregnant while using this medicine.
- feel that you are getting breathless or wheezy more often than normal, or if you are using a quick-acting inhaler (such as VENTOLIN) more than usual.

Things you should not do

- Do not stop using this medicine suddenly or change the dosage without medical advice.
- Do not use TRELEGY ELLIPTA 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.
- You should stop taking any long-acting inhalers which contain inhaled corticosteroids or bronchodilators. However, you can continue to use a quick-acting inhaler (such as VENTOLIN) during an acute episode.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRELEGY ELLIPTA affects you.

Looking after your medicine

- Store in the original package container in order to protect from moisture and do not open the foil lid until ready to inhale for the first time.
- If you store in a refrigerator allow the inhaler to return to room temperature for at least an hour before use.

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

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C.

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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Safely throw away TRELEGY ELLIPTA one month after you open the foil tray or when the counter reads "0", whichever comes first. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

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 or if the packaging is torn or shows signs of tampering.

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.

Your doctor will consider the risk of side effects when deciding which strength of TRELEGY ELLIPTA you should use.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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>Nervous system disorders:</p> <ul style="list-style-type: none"> • headache • changes in taste • tremor <p>Infections and infestations:</p> <ul style="list-style-type: none"> • sore, raised patches in the mouth or throat caused by a fungal infection (<i>candidiasis</i>) • infection of the upper airways <p>Immune system:</p> <ul style="list-style-type: none"> • flu (influenza) • common cold 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>If you experience a fungal infection of the mouth or throat, rinsing your mouth out</p>

Less serious side effects	What to do
<p>Respiratory, thoracic and mediastinal disorders:</p> <ul style="list-style-type: none"> • cough • hoarseness • itchy, runny or blocked nose • pain in the back of the mouth and throat <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> • joint and back pain • muscle spasms <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • dry mouth • constipation <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • feeling anxious 	<p>with water immediately after using TRELEGY ELLIPTA may help stop this side effect developing.</p> <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Respiratory, thoracic, and mediastinal disorders:</p> <ul style="list-style-type: none"> • infection of the lungs (<i>pneumonia</i>). Symptoms include fever, chills, increased mucous production, change in mucous colour, increased cough or increased breathing difficulties. • inflammation of the lungs (bronchitis) • inflammation of the sinuses • infection of the nose, sinuses or throat • immediate breathing difficulties and wheezing <p>Allergic reaction:</p> <p>Symptoms of an allergic reaction usually include some or all of the following:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing, coughing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body (angioedema) • rash, itching, redness or hives on the skin (urticaria) • suddenly feeling weak or light headed (may lead to collapse or loss of consciousness) <p>Musculoskeletal and connective tissue disorders:</p>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> weakening of the bones (osteoporosis), leading to risk of fractures <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none"> increase in blood sugar (<i>hyperglycaemia</i>). This may lead to increased thirst, frequent urination, or unexplained tiredness. painful and frequent urination (may be signs of a urinary tract infection) difficulties passing urine (urinary retention) pain or discomfort passing urine (<i>dysuria</i>) <p>Cardiac disorders:</p> <ul style="list-style-type: none"> irregular heartbeat faster heartbeat or awareness of heartbeat (palpitations) <p>Eye disorders:</p> <ul style="list-style-type: none"> blurred vision increased eye pressure eye pain 	<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>

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 via <https://pophealth.my.site.com/carmreportnz/s/>

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 TRELEGY ELLIPTA contains

Active ingredient (main ingredient)	Fluticasone furoate Umeclidinium (as bromide) Vilanterol (as trifenate)
Other ingredients (inactive ingredients)	Lactose monohydrate (milk protein) Magnesium stearate
Potential allergens	Lactose or milk protein

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

What TRELEGY ELLIPTA looks like

TRELEGY ELLIPTA is inhaled through the mouth using the Ellipta device. The active ingredients are in separate blisters in powder form inside the device. TRELEGY ELLIPTA 100/62.5/25 micrograms contains either 14 or 30 blisters on each strip, and so each device contains either 14 or 30 doses depending on which pack size you have been given.

TRELEGY ELLIPTA 200/62.5/25 micrograms contains 30 blisters on each strip, and each device contains 30 doses.

The Ellipta device itself is a plastic inhaler with a light grey body, a beige mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable lid foil. The active ingredients are in separate blisters in powder form inside the device.

The tray contains a desiccant sachet, to reduce moisture in the packaging. Once you have opened the lid of the tray, throw the desiccant away – do not open, eat or inhale it.

TRELEGY ELLIPTA 100/62.5/25 fluticasone 100 microgram / umeclidinium bromide 62.5 microgram / vilanterol (as trifenate) 25 microgram powder for inhalation (TT50-10360).

TRELEGY ELLIPTA 200/62.5/25 fluticasone 200 microgram / umeclidinium bromide 62.5 microgram / vilanterol (as trifenate) 25 microgram powder for inhalation (TT50-10360a).

Who distributes TRELEGY ELLIPTA

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

Trade marks are owned by or licensed to the GSK group of companies.

© 2024 GSK group of companies or licensor.

This leaflet was prepared in October 2024.

Version 7.0