

ANORO ELLIPTA

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 ANORO ELLIPTA?

ANORO ELLIPTA contains the active ingredients umeclidinium bromide and vilanterol trifenate. ANORO ELLIPTA is used to treat chronic obstructive pulmonary disease (COPD).

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

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

Do not use if you have ever had an allergic reaction to ANORO ELLIPTA or any of the ingredients listed at the end of the CMI. Do not use ANORO ELLIPTA if you are allergic or hypersensitive to lactose or milk protein.

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 ANORO ELLIPTA?](#) In the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANORO 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 ANORO ELLIPTA?

- The usual dose is one inhalation once a day.
- Use ANORO ELLIPTA at the same time each day.

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

5. What should I know while using ANORO ELLIPTA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ANORO ELLIPTA.• Tell your doctor immediately if you become pregnant or intend to become pregnant whilst using ANORO ELLIPTA.• Tell your doctor if you feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler (e.g. Ventolin) more than usual.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dosage unless your doctor tells you to.• Do not take any other medicines to help you breathe without first checking with your doctor.
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 ANORO ELLIPTA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight.• If you store it in the refrigerator allow the inhaler to return to room temperature at least 1 hour before you use it.• Do not open the foil lid until you are ready to use the inhaler for the first time.• Once ANORO ELLIPTA has been removed from the tray you may store it for a maximum period of six weeks or when your counter reads "0", whichever occurs first.

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

6. Are there any side effects?

Side effects that have been reported include sore throat with or without a runny nose, cough, constipation, dry mouth, painful and frequent urination (may be signs of a urinary tract infection), feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses known as sinusitis), pain and irritation in the back of the mouth and throat, infection of the upper airways.

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.

ANORO ELLIPTA

Active ingredient(s): *umeclidinium (as bromide) and vilanterol (as trifenate)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ANORO ELLIPTA?

ANORO ELLIPTA contains the active ingredients **umeclidinium bromide and vilanterol trifenate**.

ANORO ELLIPTA belongs to a group of medicines called bronchodilators. The active ingredients in ANORO ELLIPTA work together to help open the airways and make it easier to breathe.

ANORO ELLIPTA is used to treat **chronic obstructive pulmonary disease (COPD)**.

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

When ANORO ELLIPTA is used regularly, it can help to control the breathing difficulties related to your disease and minimise the effects of the disease on your everyday life.

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

Warnings

Do not use ANORO ELLIPTA if:

- you are allergic to umeclidinium bromide or vilanterol trifenate, 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 have a severe lactose or milk-protein allergy

Do not use ANORO ELLIPTA to relieve a sudden attack of breathlessness or wheezing. If this happens to you, you must use a quick-acting inhaler (e.g. Ventolin).

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other medical conditions
- have asthma (do not use ANORO ELLIPTA to treat asthma)
- have heart problems or high blood pressure
- have an eye problem called narrow-angle glaucoma

- have an enlarged prostate, difficulty passing urine or a blockage in your bladder

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.

It is unknown whether the active ingredients in ANORO ELLIPTA can pass into breast milk.

Children and adolescents

- Do not use ANORO ELLIPTA in children or adolescents below the age of 18 years.

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 ANORO ELLIPTA and affect how it works. These include:

- medicines called beta blockers which are used to treat high blood pressure or other heart problems
- ketoconazole, a medicine used to treat fungal infections

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

4. How do I use ANORO ELLIPTA?

How much to use

- The usual dose is one inhalation a day.
- Follow the instructions provided and use ANORO ELLIPTA until your doctor tells you to stop.

When to use ANORO ELLIPTA

- ANORO ELLIPTA should be taken at the same time every day. This will help to keep you symptom free during the day and night.

How to use ANORO ELLIPTA

- Full instructions for using ANORO ELLIPTA are given on the leaflet inside the pack.
- You inhale the medicine into your lungs through your mouth using the inhaler.
- ANORO ELLIPTA is ready to use straight away. There is no need to prepare or check the inhaler before use.
- After using the inhaler, you may clean the mouthpiece using a dry tissue, before closing the cover. Do not immerse ANORO ELLIPTA in water.

If you forget to use ANORO ELLIPTA

ANORO ELLIPTA should be used regularly at the same time every day.

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, use it as soon as you remember, then go back to using it as you normally would.

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

- If you become wheezy or breathless or develop any other symptoms of an asthma attack, use a fast-acting inhaler (e.g. Ventolin) and seek medical advice.

If you use too much ANORO ELLIPTA

If you think that you have used too much ANORO ELLIPTA, you may need urgent medical attention. If you have taken too much you might 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 13 11 26 in Australia**), 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.

5. What should I know while using ANORO ELLIPTA?

Things you should do

Call your doctor straight away if you:

- become pregnant or intend to become pregnant.
- feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler (e.g. Ventolin) more than usual.

Remind any doctor, dentist or pharmacist you visit that you are using ANORO ELLIPTA.

Things you should not do

- Do not stop using this medicine or change the dosage unless your doctor tells you to.
- Do not use ANORO ELLIPTA to treat any other complaints.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.
- Do not take any other medicines to help you breathe without first checking with your doctor.

Driving or using machines

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

Looking after your medicine

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

Do not open the foil lid until you are ready to use the inhaler for the first time.

Store it in the original package container in a cool dry place (below 30°C) 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.

If you store it in the refrigerator allow the inhaler to return to room temperature at least 1 hour before you use it.

Keep it where young children cannot reach it.

When to discard your medicine

Safely throw away ANORO ELLIPTA six weeks after you open the foil tray or when your counter reads “0”, whichever occurs first.

Write the date the inhaler should be discarded on the label in the space provided. The date should be written down 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.

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.

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using ANORO ELLIPTA, stop using it immediately and seek 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
<ul style="list-style-type: none">• sore throat with or without a runny nose• cough• constipation• dry mouth• painful and frequent urination (may be signs of a urinary tract infection)• feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses known as sinusitis)• pain and irritation in the back of the mouth and throat• infection of the upper airways• hoarse voice	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• allergic reactions Symptoms of an allergic reaction include wheezing, coughing, swelling of the lips/mouth, tongue or throat,	Call your doctor straight away, or go straight to the

Serious side effects	What to do
<p>difficulty in breathing, hives or skin rash, fainting, suddenly feeling weak or light headed.</p> <ul style="list-style-type: none"> • immediate breathing difficulties and wheezing • decrease in vision or pain in your eyes (possible signs of glaucoma) • blurred vision • increase of the measured eye pressure • difficulty in passing urine (urinary retention) • pain or discomfort when passing urine (dysuria) • irregular heartbeat, fast heartbeat, awareness of your heartbeat (palpitations) • anxiety and feeling anxious • tremor, muscle spasms • changes in taste 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

packaging. Throw the desiccant away once you have opened the tray. Do not open, eat or inhale it.

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Who distributes ANORO ELLIPTA

ANORO ELLIPTA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

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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 in Australia.

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 ANORO ELLIPTA contains

Active ingredients (main ingredients)	umeclidinium bromide vilanterol trifenate
Other ingredients (inactive ingredients)	lactose monohydrate (which contains milk proteins) magnesium stearate
Potential allergens	lactose monohydrate (which contains milk proteins)

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

What ANORO ELLIPTA looks like

ANORO ELLIPTA is supplied in a plastic inhaler with a light grey body and red mouthpiece cover containing two strips of blisters each containing a white powder. The active substances are in separate blisters in powder form inside the device. The pack contains either 7 or 30 blisters. The tray contains a desiccant sachet to reduce moisture in the