

ANORO[®] ELLIPTA[®]

Umeclidinium (as bromide) 62.5 micrograms and vilanterol (as trifenate) 25 micrograms per inhalation

Australia and New Zealand Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using ANORO ELLIPTA.

This leaflet answers some common questions about ANORO ELLIPTA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ANORO ELLIPTA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ANORO ELLIPTA is used for

ANORO ELLIPTA is used to treat chronic obstructive pulmonary disease (COPD). To use ANORO ELLIPTA, you breathe it into your lungs through your mouth using the ELLIPTA inhaler.

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

ANORO ELLIPTA contains two active ingredients: umeclidinium bromide and vilanterol trifenate.

Umeclidinium bromide and vilanterol trifenate belongs to a group of medicines called bronchodilators. Umeclidinium and vilanterol work together to help open the airways and make it easier for air to get in and out of the lungs. This will help relieve symptoms of COPD. 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.

ANORO 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 ANORO 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.

ANORO ELLIPTA should not be given to children or adolescents below the age of 18 years.

Before you use ANORO ELLIPTA

When you must not use it

Don't use ANORO ELLIPTA

- **if you are allergic (hypersensitive) to lactose or milk protein**

- **if you are allergic (hypersensitive) to umeclidinium bromide, vilanterol trifenate or any other ingredients of ANORO ELLIPTA (listed at the end of this leaflet).**

If you think either of these applies to you, don't use ANORO ELLIPTA until you have checked with your doctor.

Some of the symptoms of an allergic reaction may include:

- 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.

ANORO ELLIPTA contains lactose .

If you have been diagnosed with an intolerance to some sugars, or to milk protein, talk to your doctor before you use ANORO ELLIPTA.

If you are pregnant, if you think you may be pregnant or if you are planning to have a baby, don't use ANORO ELLIPTA without asking your doctor.

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

If you are breast-feeding, check with your doctor before you take ANORO ELLIPTA.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Talk to your doctor before you use ANORO ELLIPTA:

- if you have asthma (do not use ANORO ELLIPTA to treat asthma)
- if you have heart problems or high blood pressure
- if you have an eye problem called narrow-angle glaucoma
- if you have an enlarged prostate, difficulty passing urine or a blockage in your bladder.

Check with your doctor before you use ANORO ELLIPTA if you think any of these apply to you.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect how ANORO ELLIPTA works, or make it more likely that you'll have side effects. These include:

- medicines called beta blockers, to treat high blood pressure or other heart problems
- ketoconazole, to treat fungal infections.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use ANORO ELLIPTA

Follow all directions given to you by your doctor or pharmacist carefully.

If you do not understand the instructions in the user leaflet, ask your doctor or pharmacist for help.

How much to use

Always use ANORO ELLIPTA exactly as your doctor has told you to. Check with your doctor, nurse or pharmacist if you're not sure.

The dose is one inhalation every day at the same time of day.

How to use the inhaler

The full instructions for using ANORO ELLIPTA are given on a leaflet inside the pack.

ANORO ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.

Do not open ANORO ELLIPTA until you are ready to use it for the first time.

After using ANORO ELLIPTA, you may clean the mouthpiece, using a dry tissue, before you close the cover. Do not immerse ANORO ELLIPTA in water.

When to use it

Use ANORO ELLIPTA regularly.

It is very important that you use ANORO ELLIPTA every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

If you feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler (such as VENTOLIN) more than usual, see your doctor.

How long to use it

Don't stop ANORO ELLIPTA without medical advice.

Use ANORO ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Don't stop unless your doctor advises you to, even if you feel better.

If you forget to take it

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.

Don't take an extra dose to make up for a missed dose.

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

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

In New Zealand, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) if you think that you or anyone else may have taken too much ANORO ELLIPTA.

In Australia, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much ANORO ELLIPTA. Do this even if there are no signs of discomfort or poisoning.

If you accidentally take a larger dose of ANORO ELLIPTA than your doctor has instructed, you may notice that your heart is beating faster than usual, you feel shaky or have a headache.

While you are using ANORO ELLIPTA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ANORO ELLIPTA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take ANORO 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 stop taking your medicine or lower the dosage without checking with your doctor.

Do not take any other medicines for your breathing problems without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how ANORO ELLIPTA affects you.

Side effects

Like all medicines, ANORO ELLIPTA can cause side effects, although not everybody gets them.

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your ANORO ELLIPTA,

stop using it immediately, and seek medical help immediately.

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

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects

These may affect up to 1 in 10 people:

- sore throat with or without 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 called sinusitis)
- pain and irritation in the back of the mouth and throat
- infection of the upper airways.

Uncommon side effects

These may affect up to 1 in 100 people:

- irregular heartbeat
- faster heart beat
- awareness of heart beat (palpitations)
- anxiety
- tremor
- taste disturbance
- muscle spasms
- rash (allergic reactions).

Rare side effects

These may affect up to 1 in 1,000 people:

- allergic reactions
- immediate breathing difficulties and wheezing

- decrease in vision or pain in your eyes due to high pressure (possible signs of glaucoma)
- blurred vision
- increase of the measured eye pressure
- difficulties passing urine (urinary retention)
- pain or discomfort when passing urine (dysuria)
- hoarseness.

If you think you are having an allergic reaction to ANORO ELLIPTA, stop using this medicine and tell your doctor immediately or go to the accident and emergency department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing, coughing
- swelling of the lips/mouth, tongue or throat
- difficulty in breathing
- hay fever lumpy rash ("hives") or redness
- fainting, suddenly feeling weak or light headed

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

After using ANORO ELLIPTA

Storage

Do not use ANORO ELLIPTA after the expiry date shown on the pack.

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.

Safely throw away ANORO ELLIPTA six weeks after you open the foil tray or when your 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.

Keep your inhaler in 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.

Do not store ANORO ELLIPTA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ANORO ELLIPTA is inhaled through the mouth using the ELLIPTA device. The active substances are in separate blisters in powder form inside the device. There are either 7 or 30 blisters on each strip, and so each device contains either 7 or 30 doses depending on which pack size you have been given.

The ELLIPTA device itself is a plastic inhaler with a light grey body, a red mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet,

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

Ingredients

The active ingredients in ANORO ELLIPTA are umeclidinium (as bromide) and vilanterol (as trifenate).

Each dose contains 62.5 micrograms of the active ingredient umeclidinium. Each dose also contains 25 micrograms of the active ingredient vilanterol.

ANORO ELLIPTA also contains the inactive ingredients:

- lactose monohydrate (which contains milk proteins)
- magnesium stearate.

Supplier

Your ANORO ELLIPTA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford Victoria 3067
Australia.

Your ANORO ELLIPTA is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
New Zealand.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information

groups and books, for example in public libraries.

This leaflet was prepared on 4 April 2017.

The information provided applies only to: ANORO® ELLIPTA®.

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ANORO ELLIPTA 62.5/25 micrograms - AUST R 207529

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Version 7.0