

INCRUSE[®] ELLIPTA[®]

Umeclidinium (as bromide) 62.5 micrograms per inhalation

Australian and New Zealand Consumer Medicine Information

What is in this leaflet

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

This leaflet answers some common questions about INCRUSE 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 INCRUSE 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 INCRUSE ELLIPTA is used for

INCRUSE ELLIPTA is used to treat chronic obstructive pulmonary disease (COPD). To use INCRUSE 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.

INCRUSE ELLIPTA contains the active ingredient umeclidinium.

Umeclidinium belongs to a group of medicines called *bronchodilators*. Umeclidinium helps open the airways and make it easier for air to get in and out of the lungs. This will help relieve symptoms of COPD, a serious, long-term lung disease characterised by breathing difficulties. When INCRUSE 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.

INCRUSE 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 INCRUSE 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.

This medicine is not expected to affect your ability to drive a car or operate machinery.

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

Before you use INCRUSE ELLIPTA

When you must not use it

Don't use INCRUSE ELLIPTA

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

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing, coughing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, redness or hives on the skin
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

INCRUSE 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 INCRUSE ELLIPTA.

If you are pregnant, if you think you may be pregnant or if you are

planning to have a baby, don't use INCRUSE ELLIPTA without asking your doctor.

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

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

It is not known whether the ingredients of INCRUSE 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 INCRUSE ELLIPTA:

- if you have asthma (do not use INCRUSE 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 INCRUSE 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.

How to use INCRUSE 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 INCRUSE 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 of INCRUSE ELLIPTA once daily at the same time each day.

Don't use more than your doctor tells you to use. The dose should not exceed one inhalation per day.

How to use the inhaler

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

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

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

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

When to use it

Use INCRUSE ELLIPTA regularly.

It is very important that you use INCRUSE 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 more than usual, see your doctor.

How long to use it

Don't stop INCRUSE ELLIPTA without medical advice.

Use INCRUSE 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 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 INCRUSE ELLIPTA. Do this even if there are no signs of discomfort or poisoning.

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 INCRUSE ELLIPTA.

If you accidentally take a larger dose of INCRUSE ELLIPTA than your doctor has instructed, you may notice that your heart is beating faster than usual, you have a dry mouth or have problems with your vision and focusing on objects.

While you are using INCRUSE 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 INCRUSE 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.

Your doctor should give you a personal Action Plan to help manage your COPD. This plan will include what medicines to take regularly to control your COPD, as well as what "reliever" medicines to use when you have sudden attacks of breathlessness or wheezing.

Things you must not do

Do not take INCRUSE 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 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 INCRUSE ELLIPTA affects you.

Side effects

Like all medicines, INCRUSE 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 INCRUSE ELLIPTA, stop using it immediately, and seek medical help immediately.

If you experience eye pain or discomfort, blurred vision, visual halos or coloured images in association with red, swollen or watery eyes, these could be signs and symptoms of acute narrow-angle glaucoma. Seek medical help immediately if any of these signs or symptoms develop.

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:

- 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)
- combination of sore throat and runny nose
- faster heart beat
- cough

- infection of the upper airways
- taste disturbance.

Uncommon side effects

These may affect **up to 1 in 100** people:

- irregular heartbeat
- constipation
- dry mouth
- allergic reactions.

Rare side effects

These may affect **up to 1 in 1000** people:

- eye pain
- blurred vision
- decrease in vision or pain in your eyes due to high pressure (possible signs of glaucoma)
- difficulties in or unable to pass urine.

If you think you are having an allergic reaction to INCRUSE 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:

- shortness of breath
- wheezing, coughing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, redness or hives on the skin
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

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 INCRUSE ELLIPTA

Storage

Do not use INCRUSE 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 INCRUSE 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 INCRUSE 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

INCRUSE ELLIPTA is inhaled through the mouth using the ELLIPTA device. The active substance is 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 has been given.

The ELLIPTA device itself is a plastic inhaler with a light grey body, a light green 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 ingredient in INCRUSE ELLIPTA is umeclidinium.

Each dose contains 62.5 micrograms of the active ingredient umeclidinium (as bromide).

INCRUSE ELLIPTA also contains the inactive ingredients:

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

Supplier

INCRUSE ELLIPTA is supplied in Australia by:

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

INCRUSE ELLIPTA is supplied in New Zealand by:

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
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: INCRUSE® ELLIPTA®.

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