

# INCRUSE ELLIPTA

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## 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.

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### 1. Why am I using INCRUSE ELLIPTA?

INCRUSE ELLIPTA contains the active ingredient umeclidinium. INCRUSE ELLIPTA is used to treat chronic obstructive pulmonary disease (COPD).

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

### 2. What should I know before I use INCRUSE ELLIPTA?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with INCRUSE 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 INCRUSE ELLIPTA?

- The usual dose of INCRUSE ELLIPTA for COPD is one inhalation daily at the same time.

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

### 5. What should I know while using INCRUSE ELLIPTA?

#### Things you should do

- Remind any doctor, dentist, pharmacist or nurse you visit that you are using INCRUSE ELLIPTA.
- Tell your doctor immediately if you become pregnant or intend to become

	<p>pregnant whilst using INCRUSE ELLIPTA.</p> <ul style="list-style-type: none"> <li>• 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 more than usual.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.</li> <li>• Do not take any other medicines to help you breathe without first checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how INCRUSE ELLIPTA affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight.</li> <li>• If you store it in the refrigerator allow the</li> </ul>

inhaler to return to room temperature at least 1 hour before you use it.

- Safely throw away INCRUSE ELLIPTA six weeks after you open the foil tray or when the counter reads "0", whichever comes first.

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

## 6. Are there any side effects?

Side effects that have been reported include 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 heartbeat, cough, infection of the upper airways, taste disturbance.

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.

# INCRUSE ELLIPTA

**Active ingredient(s):** *Umeclidinium (as bromide)*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I using INCRUSE ELLIPTA?

**INCRUSE ELLIPTA contains the active ingredient umeclidinium.**

**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.

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.

## **2. What should I know before I use INCRUSE ELLIPTA?**

### **Warnings**

#### **Do not use INCRUSE ELLIPTA if:**

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

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)

#### **Check with your doctor if you:**

- have asthma (do not use INCRUSE 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.

- have been diagnosed with an intolerance to some sugars, or to milk protein

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.

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

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

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

## **Children**

- INCRUSE ELLIPTA should not be given to 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 Incruse Ellipta and affect how it works.**

## **4. How do I use INCRUSE ELLIPTA?**

### **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.

### **When to use INCRUSE ELLIPTA**

- INCRUSE ELLIPTA should be used 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.
- INCRUSE ELLIPTA should be used at the same time each day.

### **How to use INCRUSE ELLIPTA**

- Full instructions for using INCRUSE ELLIPTA are present in the leaflet in 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.

## **If you forget to use INCRUSE ELLIPTA**

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

**Do not take a double 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 your quick acting inhaler (eg: VENTOLIN), then seek medical advice.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use 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.

**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.**

## **5. What should I know while using INCRUSE ELLIPTA?**

### **Things you should do**

**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:**

- If you become pregnant while taking this medicine
- 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.

**Remind any doctor, dentist, pharmacist or nurse you visit that you are using INCRUSE ELLIPTA.**

## **Things you should not do**

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- 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 take any other medicines for your breathing problems without checking with your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how INCRUSE 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.

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

Store it in a cool dry place where the temperature stays 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.**

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

### **When to discard your medicine**

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.

### **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 printed on the pack or if the packaging is torn or shows signs of tampering.

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

## **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.

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.

## **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Infections:</b> <ul style="list-style-type: none"><li>● painful and frequent urination (may be signs of a urinary tract infection)</li><li>● infection of the upper airways</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)</li> </ul> <p><b>Heart disorders:</b></p> <ul style="list-style-type: none"> <li>● faster or irregular heartbeat</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>● constipation</li> </ul> <p><b>Respiratory and Mouth disorders:</b></p> <ul style="list-style-type: none"> <li>● cough</li> <li>● combination of sore throat and runny nose</li> <li>● dry mouth</li> <li>● taste disturbance</li> <li>● mouth and throat pain</li> <li>● hoarseness</li> </ul> <p><b>Eye disorders:</b></p> <ul style="list-style-type: none"> <li>● eye pain</li> <li>● blurred vision</li> <li>● decrease in vision or pain in your eyes due to high pressure (possible signs of glaucoma)</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<b>Urinary disorders:</b> <ul style="list-style-type: none"> <li>• difficulty passing urine</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<b>Allergic reaction:</b> <ul style="list-style-type: none"> <li>• Symptoms of an allergic reaction usually 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 and suddenly feeling weak or lightheaded (may lead to collapse or loss of consciousness).</li> </ul>	<b>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.</b>

**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](http://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 INCRUSE ELLIPTA] contains

<b>Active ingredient (main ingredient)</b>	umeclidinium (as bromide). Each dose contains 62.5 micrograms.
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate magnesium stearate

<b>Potential allergens</b>	lactose monohydrate (which contains milk proteins)
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What INCRUSE ELLIPTA 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.

INCRUSE ELLIPTA: AUST R 211601.

## **Who distributes INCRUSE ELLIPTA**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Phone: 1800 033 109

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