

**Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed according to a physician's prescription only

Incruse Ellipta 55 mcg, Inhalation powder

Each dose released from the Incruse Ellipta inhaler contains 55 micrograms of the active ingredient, Umeclidinium (equivalent to 65 micrograms of umeclidinium bromide).

For the list of the inactive and allergenic ingredients, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Incruse Ellipta contains the active substance umeclidinium.

This medicine is used to treat *chronic obstructive pulmonary disease (COPD)* in adults. COPD is a long-term condition in which the airways and air sacs in the lungs gradually become blocked or damaged, leading to breathing difficulties that slowly get worse. Tightening of the muscles around the airways narrows the airways and restricts the flow of air, thereby adding to breathing difficulties.

This medicine blocks the tightening of these muscles, making it easier for air to get in and out of the lungs. When used regularly, it can help control your breathing difficulties and reduce the effects of COPD 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 reliever inhaler (such as salbutamol).

If you do not have a quick-acting inhaler, contact your physician.

Therapeutic group: anticholinergic.

Incruse Ellipta belongs to a group of medicines called bronchodilators.

2. Before using the medicine

Do not use the medicine if:

- You are **sensitive (allergic)** to umeclidinium or to any of the additional ingredients contained in the medicine (*listed in section 6*).
- If you think the above applies to you, **do not use** this medicine until you have checked with your physician.

Special warnings regarding the use of the medicine

Before the treatment with Incruse Ellipta, tell the physician if:

- you have **asthma** (do not use Incruse Ellipta to treat asthma)
- you have **heart problems**
- you have an eye problem called **narrow-angle glaucoma**
- you have an **enlarged prostate, difficulty passing urine** or a **blockage in your bladder**
- you have **severe liver problems**

→ **Check with your physician** if you think any of these apply to you.

Breathing difficulties immediately after use of Incruse Ellipta

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your Incruse Ellipta inhaler:

→ **Stop using this medicine and seek medical help immediately, as you may have a serious condition called paradoxical bronchospasm.**

Eye problems during treatment with Incruse Ellipta

If you get eye pain or discomfort, temporary blurring of vision, see visual halos or coloured images in association with red eyes during treatment with Incruse Ellipta:

→ **Stop using this medicine and seek medical help immediately, these may be signs of an acute attack of narrow-angle glaucoma.**

Children and adolescents

Do not give this medicine to **children or adolescents below the age of 18 years.**

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. If you are not sure what your medicine contains, talk to your physician or pharmacist.

In particular, tell the physician or pharmacist if you are taking other long-acting medicines similar to this medicine for breathing problems, e.g., tiotropium. You should not use Incruse Ellipta together with these other medicines. If you are not sure what your medicine contains, talk to your physician or pharmacist.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, **consult with your physician** before using this medicine. Do not use this medicine if you are pregnant, unless your physician tells you so.

It is not known whether the ingredients of Incruse Ellipta can pass into breast milk. **If you are breast-feeding, you must check with your physician** before you use Incruse Ellipta.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or operate

machines.

Important information about some of the ingredients of the medicine **Incruse Ellipta contains lactose**

If you have been told by your physician that you have an intolerance to some sugars, talk to your physician before using this medicine.

3. How should you use the medicine?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined only by the physician.

The usual dosage is generally one inhalation every day at the same time of day. You only need to inhale once a day because the effect of this medicine lasts for 24 hours.

Do not exceed the recommended dose.

Use Incruse Ellipta regularly

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

Do **not** use Incruse Ellipta to relieve a **sudden attack of breathlessness or wheezing**. If you get this sort of attack, you must use a quick-acting reliever inhaler (such as salbutamol).

How to use the Ellipta inhaler

See '*Step-by-step instructions for use*' after section 6 in this leaflet for full information.

Incruse Ellipta is intended for inhalation use. To use Incruse Ellipta, inhale it into your lungs through the mouth, using the Ellipta inhaler.

If your symptoms do not improve

If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using a quick-acting reliever inhaler more often:

→ **Contact your physician as soon as possible.**

If you accidentally took a higher dosage

Contact your physician or pharmacist for advice immediately as you may need medical attention. If possible, show them the inhaler, the package or this leaflet. You may notice that your heart is beating faster than usual, you have visual disturbances or a dry mouth.

If you took an overdose or if a child has accidentally taken the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to use the medicine

If you forgot to use this medicine at the designated time, **do not inhale a double dose to make up for a forgotten dose**. Inhale your next dose at the

usual time.

If you start wheezing or become breathless, use a quick-acting reliever inhaler (such as salbutamol); then seek medical advice.

Adhere to the treatment as recommended by the physician.

If you stop using the medicine

Use this medicine for as long as your physician recommends. It will only be effective as long as you are using it. Do not stop unless your physician advises you to, even if you feel better, as your symptoms may get worse.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Incruse Ellipta may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Allergic reactions

Allergic reactions are uncommon (may affect up to 1 in 100 people).

If you have any of the following symptoms after using Incruse Ellipta, **stop using this medicine and tell your physician immediately:**

- itching
- skin rash (itchy lumps - hives) or redness.

Common side effects

These may affect **up to 1 in 10** people:

- faster heart beat
- frequent and painful urination (may be a sign of a urinary tract infection)
- common cold
- infection of the nose and throat
- cough
- feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)
- headache
- constipation.

Uncommon side effects

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

- irregular heart beat
- sore throat
- dry mouth
- rash
- taste disturbance.

Rare side effects

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

- eye pain.

Other side effects

Other side effects that have appeared in a very small number of people, but whose exact frequency of occurrence is unknown (cannot be estimated from the existing data):

- decreased vision or pain in the eyes due to high pressure in the eyes (possible signs of glaucoma)
- blurred vision
- increase in the measured intraocular pressure
- difficulty and pain when passing urine - these may be signs of bladder obstruction or urinary retention
- dizziness.

If a side effect occurred, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store the inhaler in the original package in order to protect from moisture and only take it out immediately before first use. Do not open the tray until the start of use. Once the tray is opened, the inhaler can be used for up to 6 weeks, starting from the date of opening the tray. When taking the inhaler out of the tray, the “Discard by” date should be written on the back label of the inhaler and carton box, in the designated spot.
- Do not store above 30°C.
- If your inhaler is stored in a refrigerator, allow it to return to room temperature for at least one hour before use.
- Do not discard medicines in the wastewater or household waste. Consult the pharmacist as to how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient, the medicine also contains – Magnesium stearate, lactose monohydrate (see section 2 under ‘Incruse Ellipta contains lactose’).

- What the medicine looks like and the content of the package – Incruse Ellipta is an inhalation powder.

The Ellipta inhaler consists of a grey plastic body, a light green mouthpiece cover and a dose counter. It is packaged in a tray with a peelable aluminum cover. The tray contains a desiccant packet, to reduce moisture in the packaging.

The active ingredient is present in the form of white powder in a blister strip inside the inhaler.

Each inhaler contains either 7 or 30 doses.

Not all pack sizes may be marketed.

- **License Holder and address:** GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- **Manufacturer and address:** Glaxo Operations UK Limited (Glaxo Wellcome Operations), Ware, UK.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in July 2017, and was updated in accordance with the Ministry of Health guidelines in December 2019.

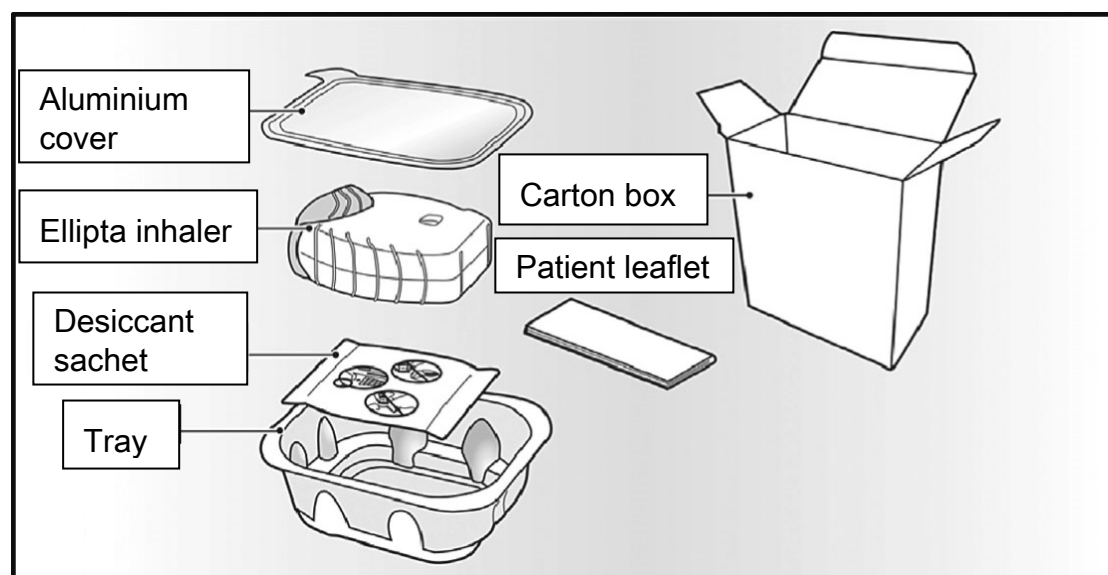
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 153-40-34134.

Step-by-step instructions for use

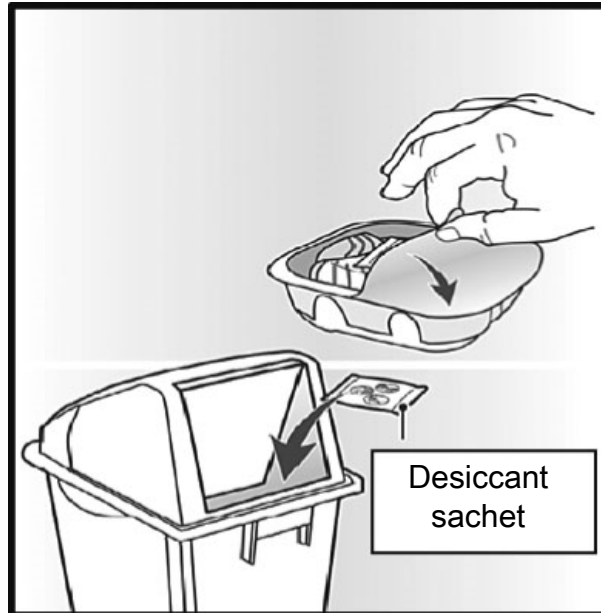
What is the Ellipta inhaler?

The first time you use Incruse Ellipta you do not need to check that the inhaler is working properly; it contains premeasured doses and is ready to use straight away.

The carton box of your Incruse Ellipta inhaler contains:



The inhaler is packaged in a tray; **do not open the tray until you are ready to start using your new inhaler.** When you are ready to use the inhaler, peel back the aluminum cover to open the tray. The tray contains a **desiccant sachet**, to reduce moisture. Throw this sachet away - **do not** open, eat or inhale it.



When you take the inhaler out of its tray, it will be in the 'closed' position. **Do not open it until you are ready to inhale a dose of medicine.** When opening the tray, write the "Discard by" date on the inhaler back label and the carton in the space provided. The "Discard by" date is 6 weeks from the date you opened the tray. After this date, the inhaler should no longer be used. The tray can be discarded after first opening.

The instructions for use of the Ellipta inhaler provided below can be used for either the 30 doses (sufficient for 30 days of treatment) or the 7 doses (sufficient for 7 days of treatment) inhaler.

1) Read this information before you start

If you open and close the cover without inhaling the medicine, you will lose the dose.

The lost dose will be securely held inside the inhaler, but it will no longer be available.

It is not possible to accidentally take an extra dose or a double dose in one inhalation.

Dose counter

This shows how many doses of medicine are left in the inhaler.

Before the inhaler has been used, it shows exactly 30 doses.

It counts down by 1 each time you open the cover.

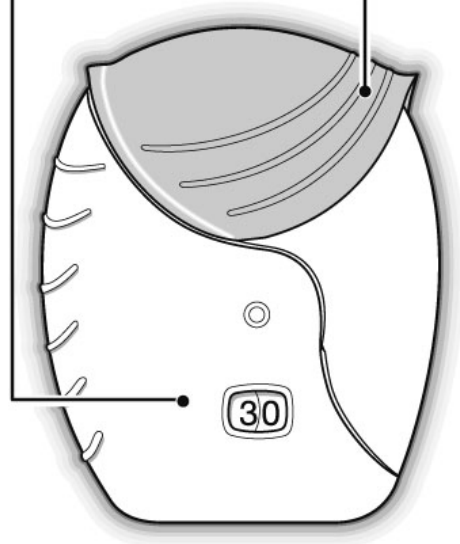
When fewer than 10 doses are left, half of the dose counter shows red.

After you have used the last dose, **half of the dose counter shows red and the number 0 is displayed.** Your inhaler is now empty.

If you open the cover after this, the dose counter will change from half red to completely red.

Cover

Each time you open this, you prepare one dose of medicine.



2) Prepare a dose

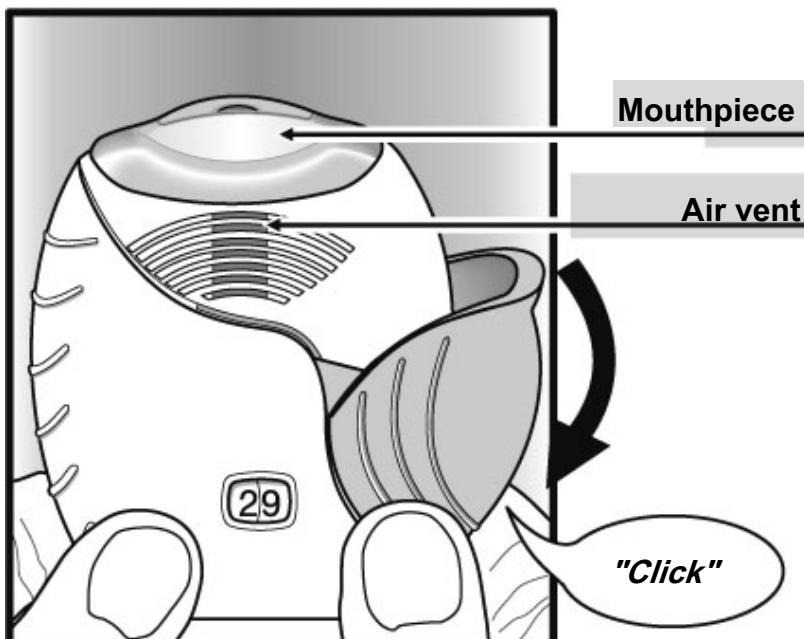
Wait to open the cover until you are ready to inhale your dose.

Do not shake the inhaler.

- **Slide the cover down until you hear a “click”.**

Your medicine is now ready to be inhaled.

The dose counter counts down by 1 to confirm.



- If the dose counter does not count down as you hear the “click”, the

inhaler will not release medicine.

Go back to your pharmacist for advice.

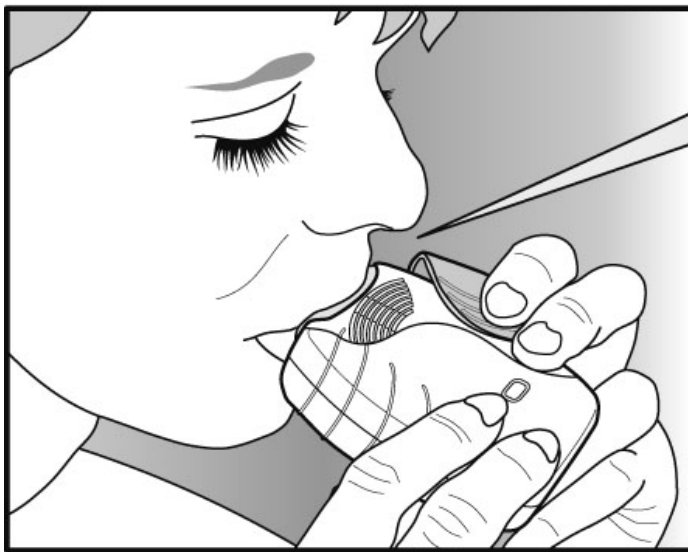
3) Inhale your medicine

- **While holding the inhaler away from your mouth, breathe out as much as you can.**

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.



Your lips fit over the contoured shape of the mouthpiece for inhaling.

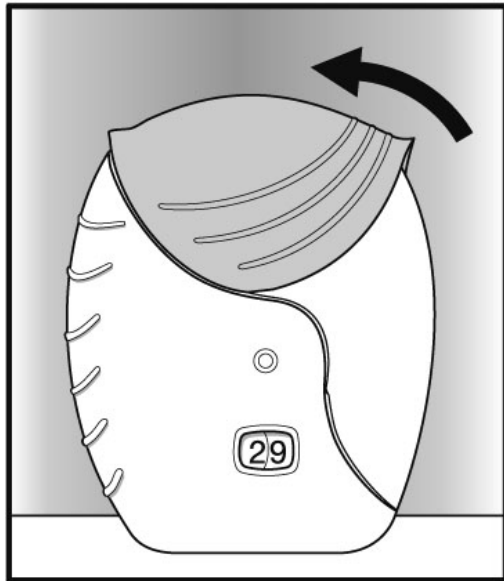
Do not block the air vent with your fingers.

- Take one long, deep and steady breath in. Hold this breath in for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

If you want to clean the mouthpiece, use a **dry tissue**, **before** you close the cover.

4) Close the inhaler



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

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