



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Incruse Ellipta<sup>1</sup> (*umeclidinium bromide*)

An overview of Incruse Ellipta and why it is authorised in the EU

### What is Incruse Ellipta and what is it used for?

Incruse Ellipta is a medicine used to relieve the symptoms of chronic obstructive pulmonary disease (COPD) in adults. COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing. Incruse Ellipta is used for maintenance (regular) treatment.

Incruse Ellipta contains the active substance umeclidinium bromide.

### How is Incruse Ellipta used?

Incruse Ellipta can only be obtained with a prescription. It is available as an inhalation powder in a portable inhaler device. Each inhalation provides 65 micrograms of umeclidinium bromide equivalent to 55 micrograms of umeclidinium.

The recommended dose is one inhalation per day at the same time each day. For detailed information on how to use the inhaler correctly, see the instructions in the package leaflet or contact your doctor or pharmacist.

### How does Incruse Ellipta work?

The active substance in Incruse Ellipta, umeclidinium bromide, is a muscarinic receptor antagonist. It works by blocking some receptors called muscarinic receptors, which control the contraction of muscles. When umeclidinium bromide is inhaled, it relaxes the muscles of the airways. This helps to keep the airways open and allows the patient to breathe more easily.

### What benefits of Incruse Ellipta have been shown in studies?

Incruse Ellipta was investigated in four main studies involving over 4,000 patients. Three studies compared Incruse Ellipta with placebo (a dummy treatment), while one study compared Incruse Ellipta with tiotropium (another medicine for COPD). The main measure of effectiveness was based on changes in the patients' forced expiratory volumes (FEV<sub>1</sub>, the maximum volume of air a person can breathe out in one second).

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<sup>1</sup> Previously known as Incruse.



Results showed that Incruse Ellipta improved lung function by an average FEV<sub>1</sub> of 127 ml more than placebo after 12 weeks of treatment and by 115 ml more than placebo after 24 weeks of treatment. A double dose of Incruse Ellipta only showed small improvements compared with a single dose, which were not considered relevant. In the study comparing Incruse Ellipta with tiotropium, FEV<sub>1</sub> improvements over 24 weeks were similar for both medicines.

The studies also showed an improvement in symptoms such as breathlessness and wheezing.

### **What are the risks associated with Incruse Ellipta?**

The most common side effects with Incruse Ellipta (which may affect up to 1 in 10 people) are headache, nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (nose and throat infection), sinusitis (inflammation of the sinuses), cough, urinary tract infection (infection of the structures that carry urine), and tachycardia (increased heart rate).

For the full list of side effects and restrictions with Incruse Ellipta, see the package leaflet.

### **Why is Incruse Ellipta authorised in the EU?**

The European Medicines Agency decided that Incruse Ellipta's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Incruse Ellipta was shown to be effective at improving lung function and symptoms of COPD. The Agency also noted that there were no major safety concerns with Incruse Ellipta, with side effects being manageable and similar to other medicines of the same class (antimuscarinic bronchodilators).

### **What measures are being taken to ensure the safe and effective use of Incruse Ellipta?**

As medicines of the same class as Incruse Ellipta may have an effect on the heart and blood vessels in the brain, the company that markets Incruse Ellipta will carry out a long-term study in patients to collect further information on its safety in comparison with tiotropium.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Incruse Ellipta have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Incruse Ellipta are continuously monitored. Side effects reported with Incruse Ellipta are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Incruse Ellipta**

Incruse Ellipta received a marketing authorisation valid throughout the EU on 28 April 2014.

Further information on Incruse Ellipta can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).

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