**Incruse**

**umeclidinium bromide**

This is a summary of the European public assessment report (EPAR) for Incruse. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Incruse.

For practical information about using Incruse, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Incruse and what is it used for?**

Incruse is a medicine that contains the active substance umeclidinium bromide. It is 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 is used for maintenance (regular) treatment.

**How is Incruse used?**

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

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.

**How does Incruse work?**

The active substance in Incruse, 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 causes the muscles of the airways to relax, helping to keep the airways open and allowing the patient to breathe more easily.
What benefits of Incruse have been shown in studies?

Incruse was investigated in four main studies involving over 4,000 patients. Three studies compared Incruse with placebo (a dummy treatment), while one study compared Incruse with tiotropium (another medicine for COPD). The main measure of effectiveness was based on changes in the patients’ forced expiratory volumes (FEV₁, the maximum volume of air a person can breathe out in one second). Results showed that Incruse at a dose of equivalent to 55 micrograms of umeclidinium improved lung function by an average FEV₁ by 127 ml more than placebo after 12 weeks of treatment and by 115 ml after 24 weeks of treatment. Incruse given at double that dose only showed small improvements compared with the lower dose, which were not considered relevant. In the study comparing Incruse with tiotropium, FEV₁ 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?

The most common side effects with Incruse (seen in between 1 and 10 patients in 100) are headache, nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (cold), sinusitis, cough, urinary tract infection, and tachycardia (increased heart rate).

For the full list of all side effects and restrictions, see the package leaflet.

Why is Incruse approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Incruse’s benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that Incruse was shown to be effective at improving the lung function and symptoms of COPD. The CHMP also noted that there were no major safety concerns with Incruse, with side effects being manageable and similar to other antimuscarinic bronchodilator medicines.

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

A risk management plan has been developed to ensure that Incruse is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Incruse, including the appropriate precautions to be followed by healthcare professionals and patients.

As antimuscarinic bronchodilator medicines may have an effect on the heart and blood vessels, the company will continue to closely monitor the medicine’s cardiovascular effects and will carry out a further study in patients to identify any potential risks.

Further information can be found in the summary of the risk management plan.

Other information about Incruse

The European Commission granted a marketing authorisation valid throughout the European Union for Incruse on 28 April 2014.

The full EPAR and risk management plan summary for Incruse can be found on the Agency’s website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more
information about treatment with Incruse, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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