

## IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Incruse®<sup>▼</sup> Ellipta® (umeclidinium inhalation powder)

### SUMMARY OF ASSESSMENT AND ITS FINDINGS, September 2015

#### BACKGROUND

Incruse®<sup>▼</sup> Ellipta® 55 micrograms (umeclidinium bromide) manufactured by GSK is a dry powder for inhalation which was launched in the UK in July 2014. UKMI has assessed this new product using the UKMI product safety tool.

The product is indicated for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). It one of three Ellipta® inhalers available the UK.

Other Ellipta® products are:

- Relvar®<sup>▼</sup> containing vilanterol trifenate and fluticasone (note: two strengths are available; the 99/22 microgram strength is licensed for COPD and asthma and the 184/22 microgram strength is licensed for asthma only) and
- Anoro®<sup>▼</sup> containing vilanterol trifenate and umeclidinium bromide

#### DETAILS OF PRODUCTS ASSESSED

Images of the Incruse®<sup>▼</sup> Ellipta® product and associated labels were assessed. In addition a dummy demonstration and training device was available. Images of the outer packaging are re-produced below.

#### CONCLUSIONS FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

The following points were raised after independent consideration of the product by two pharmacists.

- As with the other currently available Ellipta® inhalers, once the foil pack is opened and the desiccant removed, Incruse®<sup>▼</sup> Ellipta® has a relatively short in-use shelf life of 6 weeks. Whilst the shelf life does allow for complete use of the inhaler at the licenced dose, it may not facilitate efficient use should patients wish to keep more than one device in different locations. In practice, the risk of patients using an out-of-date device may be greater than with other devices, although the additional information advising patients not to open the tray until they are ready to inhale a dose may mitigate this risk.
- Two other Ellipta® devices are available, one of which contains components of the Incruse®<sup>▼</sup> product; Anoro®<sup>▼</sup> (contains umeclidinium) and therefore there is potential for confusion with each other when prescribing and dispensing, particularly if selecting from generic names on prescribing systems. This issue may of course apply to other inhaler devices which are available with similar variations of constituents.
- The generic constituent names and other details are written in 3 languages on both the device and outer labelling. This may obscure the important information and introduce a potential for confusion.
- Micrograms are stated in full and using the conventional “mcg” and the outside convention “µg”. This was stipulated in the EU labelling requirements but could introduce a potential for confusion.

#### POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

As we understand it the manufacturer of the device has recently changed the packaging to help patients use the device within the limited expiry window, but this new packaging is not currently available in the UK. Until the new packaging is launched the risk remains of patients using the medication past the in-use shelf life.

Recommendations for local users

- We recommend careful counselling and advice is provided to patients. In particular, this should ensure that they are aware that there is currently one other Ellipta®<sup>▼</sup> inhaler on the market, containing components of Incruse®<sup>▼</sup>. There are also more Ellipta® devices in the pipeline. In addition, patients should also be informed that the device has a relatively limited expiry once opened which should be marked on the label.
- Prescribing and dispensing systems (both electronic and paper-based) should be reviewed to minimise the likelihood of prescribing or selecting the wrong Ellipta® product. Particularly as new Ellipta® products are launched to the UK market.

This report was produced in September 2015 using the actual product and photographic images of Incruse®<sup>▼</sup>

Ellipta®.

This report summarises product assessments undertaken by:  
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**IMAGES OF PRODUCTS**



