IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Relvar® Ellipta®
(fluticasone furoate/vilanterol trifenatate inhalation powder)

SUMMARY OF ASSESSMENT AND ITS FINDINGS

BACKGROUND

Relvar® Ellipta® (fluticasone furoate/vilanterol trifenatate) manufactured by Glaxo Smith Kline (GSK) is a dry powder for inhalation which was launched in the UK in January 2014. It is available in two strengths: the 92/22 microgram strength is licensed for use in asthma and COPD; the 184/22 microgram strength is licensed for use in asthma only. The product forms part of a range of inhalers in the Ellipta® device; other Ellipta® products are:
- Anoro® containing umeclidinium bromide and vilanterol trifenatate.
- Incruse® containing umeclidinium bromide only.

In response to practical insights and feedback received from a number of professional and patient organisations, include a product safety assessment report by UKMi, GSK has changed the product packaging of Relvar®. These changes took effect in January 2015. Given the common practice in the UK of referring to short acting beta agonists (SABAs) as “blue inhalers”, one of the main changes to the revised packaging has been to the blue colour of the inhaler label and cap, which are now yellow.

This UKMi re-assessment of Relvar® Ellipta® has been produced in response to the various packaging changes made by GSK.

DETAILS OF PRODUCTS ASSESSED

The product was assessed using photographic images. Images of the device (including the outer packaging) for both strengths are re-produced below.

CONCLUSIONS FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

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

- The new yellow colour for Relvar® is consistent with clear differentiation between Relvar® and SABAs in clinical practice.
- The name Relvar® could potentially still cause confusion with SABAs as it remains similar to ‘reliever’; however, the colour change to yellow may now mitigate against the risk of such confusion.
- The bulk of the inhaler is yellow, with the two strengths suitably differentiated with narrow coloured stripes.
- As with the other currently available Ellipta® inhalers, once the foil pack is opened and the desiccant removed, Relvar® 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. However, the addition of the “discard by…” portion on the device is to be welcomed and may now mitigate against this risk.
- Two other Ellipta® devices are currently available, one of which contains vilanterol, a component of Relvar®. There is therefore 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 that 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 introduces a potential for confusion.
- Micrograms are stated in full and also using “mcg” and “µg”. This was stipulated in the EU labelling requirements but could introduce a potential for confusion.

To conclude, in our view the new product packaging is a significant improvement and addresses many of the safety concerns raised previously by both UKMi and other organisations. In our view the packaging and presentation of Relvar® Ellipta® is now not of significant concern.
POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

The manufacturer of the device has provided information for patients, prescribers, dispensers and nurses, highlighting the changes to colour and labelling of Relvar® Ellipta®. This information can be accessed at: http://hcp.gsk.co.uk/products/relvar/relvar-ellipta-packaging-change.html

Recommendations for local users

- Local users should familiarise themselves with the information provided by the manufacturer regarding the changes to product packaging for Relvar® as of January 2015. It is possible that patients may be in possession of Relvar® inhalers in both the new and the old packaging. Careful patient counselling by health care professionals will ensure the new packaging does not cause confusion for patients.
- Patients should be reminded that this is a regular daily dose ‘preventer’ inhaler and not a ‘when required ‘reliever’ inhaler.
- Healthcare professionals, prescribing and dispensing staff should be alerted to the fact that Relvar® comes in two strengths.
  - The 92/22 microgram strength (indicated for COPD and asthma) which has a green strip on the product packaging
  - The 184/22 microgram strength (only indicated for asthma not controlled at the 92/22 strength) which has a red strip. Long term use of this preparation may require a steroid card according to local practice.
- Patients should understand that the device has an expiry of 6 weeks once opened, and that they should complete the “discard by...” which will ensure only in-date inhalers are used.
- As with other respiratory products, prescribing and dispensing systems (both electronic and paper-based) should be reviewed to minimise the likelihood of prescribing or selecting the wrong product, particularly as new Ellipta® products are launched to the UK market.

This report was produced in January 2015 using photographic images of Relvar® Ellipta®. Images of the product were obtained from GSK.

This report summarises product assessments undertaken by:
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IMAGES OF PRODUCTS