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Our concerns with Relvar Ellipta

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From Mr T. G. D. Capstick, MRPharmS, and others

We would like to alert pharmacists to the potential for inadvertent dosing errors that may occur when patients are prescribed the new Relvar Ellipta (fluticasone furoate/vilanterol) inhaler for asthma or chronic obstructive pulmonary disease.

Pharmacists should be alert to the fact that the licensed strengths of Relvar Ellipta (92µg/22µg and 184µg/22µg) are equivalent to medium to high doses of fluticasone propionate (500µg and 1,000µg, respectively). There is no low-dose inhaled corticosteroid version available and the 92µg/22µg strength, marketed as "low to mid dose of inhaled corticosteroid" is actually at the top of the dose-response curve in asthma. Consequently Relvar Ellipta is not appropriate for patients at Step 3 of the British Thoracic Society and Scottish Intercollegiate Guidelines Network asthma guidelines.

For many years, pharmacists and other healthcare professionals have been educating patients on when to use their inhalers for asthma and COPD, and frequently use simple terms such as "reliever" or "blue inhaler" to advise patients when to use their salbutamol or terbutaline, and terms such as "preventer" or "brown, red or purple inhaler"to advise patients when to use their inhaled corticosteroid inhaler.

We are concerned that the new Relvar Ellipta inhaler will be confusing for patients because it has a blue cover and the brand name sounds similar to "reliever". This could cause patients mistakenly to use Relvar Ellipta on an "as needed" basis rather than regularly just once a day.

When we have shown pictures of the new Relvar Ellipta inhaler to patients and healthcare professionals, almost all have thought that this looked like a reliever inhaler and that it should be used when necessary for symptomatic relief.

There are other brands and generic inhalers that do not conform to the usual expected colour coding convention of inhalers, and pharmacists should be aware of these when educating patients.

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DECLARATION: In the past two years Mr Capstick has received payment for educational sessions to various healthcare professionals from GSK, Novartis, Teva, Pfizer and AstraZeneca. He has also received sponsorship from Teva to attend the European Respiratory Congress in 2014.

Hamzah Baig, respiratory medical director, GSK, responds: We would like to clarify the correct dosing and the patients who may benefit from Relvar Ellipta while addressing the other points raised. This new inhaled corticosteroid (ICS) and long-acting beta-2-agonist (LABA) combination treatment contains fluticasone furoate (FF) and vilanterol (VI), respectively. 92/22µg and 184/22µg are approved in asthma and 92/22µg in COPD patients.

FF/VI 92/22µg was granted a low-mid dose ICS licence, indicated for the regular treatment of asthma in patients ≥12 years not adequately controlled on ICS and as an "as needed" short-acting inhaled beta-2-agonist, where appropriate, and can be prescribed as such. The licence of "low-mid dose" FF/VI was granted on the basis of clinical trials that have demonstrated its effectiveness and safety in thousands of patients on low-mid ICS. FF/VI is generally well tolerated, similar to other ICS/LABAs (see summary of product characteristics). A dose of 92µg FF once daily is approximately equivalent to 250µg fluticasone propionate (FP) twice daily. The approved indication is consistent with BTS-SIGN guidance in asthma management when stepping up appropriate patients from Step 2 to Step 3.

Traditionally, ICS dose has been described according to equivalence to beclometasone dipropionate (BDP). However, the exact equivalence of FF to BDP is not known because this has not been studied. FP was used as a comparator and is relevant as the ICS component of Seretide which is the most widely used ICS/LABA in the UK, with extensive clinical safety data over 16 years. Equivalence of FP to BDP was demonstrated through bioequivalence studies whereas FF to FP equivalence was measured through improvement in lung function. Therefore, no comparison of FF to BDP can be determined.

BTS-SIGN guidance states that an absolute threshold of steroid dose for introduction of LABA add-on therapy in all patients cannot be defined and patients should be initiated on a dose suitable for disease severity, and regularly assessed for stepping down treatment where appropriate.

Relvar Ellipta is a dry powder inhaler (DPI), has a light grey body, a pale blue cap and stands up on flat surfaces. Patients and healthcare professionals were involved throughout the development of Relvar Ellipta, including shape and colour, which from the limited scope of colours should be globally accepted.

Many inhalers are metered dose inhalers (MDIs) and are distinct from DPIs in shape, operation and handling. In studies, Relvar Ellipta showed that at least 95 per cent of patients with asthma and COPD used Ellipta correctly first time after one demonstration and >99 per cent were still using it correctly at day 28.

The name "Relvar" was created to suit many languages throughout the world. This has gone through the rigorous European Medicines Agency Name Review Group approval process to review suitability and one name is authorised throughout all member states. GSK has fully complied with this strict guidance. To date, we have not observed any safety signals relating to the name or colour.

We believe that pharmacists are well placed to help support patients on the appropriate use of their medication. Further information for pharmacists is available at www.relvar.co.uk.

See also: European Medicines Agency to approach GSK after respiratory pharmacists raise concerns about Relvar Ellipta

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