

Medication Safety Updates

July 2018

Medication Safety



Esmya (ulipristal acetate) for uterine fibroids

The March 2018 MHRA Drug Safety Update reported on the temporary safety measures that have been put in place while an EU review investigates the link between cases of serious liver injury, including 4 cases requiring liver transplantation, and Esmya (ulipristal acetate) for uterine fibroids.

In light of the ongoing safety review, **East Lancashire Medicines Management Board has now changed the traffic light status of Esmya (ulipristal acetate) to BLACK traffic light, i.e. not for prescribing either in primary or secondary care.**

Prescribers are reminded that no cases of serious liver injury have been reported with ellaOne, the emergency contraceptive, which also contains ulipristal acetate and there are no concerns with this medicine at this time.

Risks with Inhaled Medications Using the Ellipta Device

Ellipta is an inhaler device, manufactured by GlaxoSmithKline (GSK). The Ellipta brand name for the inhaler device is imbedded in the drug names of products that use the device. In the UK there are Trelegy Ellipta, Relvar Ellipta, Anoro Ellipta and Incruse Ellipta.

The Institute for Safe Medication Practices, which monitors new adverse drug event reports submitted to the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) has investigated 557 adverse event reports, over a 12 month period ending with Q3 2017 with regards Ellipta inhalers.

The investigation indicated that patients, pharmacists, and physicians were confusing inhaler products with the same Ellipta device but different active ingredients. The reports indicated problems in one or more of these categories: name confusion (61.2%), dispensing errors (54.9%), and prescribing errors (15.6%). The product confusion reports indicated issues with both packaging and labelling.

While the ingredient brand names e.g. Relvar are, by design, sufficiently unique to identify the products without the inhaler device information, some practitioners and patients appear to believe the products are named Ellipta or are mixing them up because of the common Ellipta name.

Trelegy, Relvar, Anoro and Incruse are BLACK traffic light locally (i.e. Not Recommended for Use).

However, GP practices across East Lancashire CCG spent approximately £26,000 between May 2017 and April 2018 on these products.