### IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Cortiment® 9mg prolonged release tablets (budesonide)

**SUMMARY OF ASSESSMENT AND ITS FINDINGS**

#### BACKGROUND
Cortiment® 9mg prolonged release tablets, manufactured by Ferring Pharmaceuticals, were launched in the UK in April 2015. UKMI has assessed this new product using the UKMI product safety tool.

The product is licensed for inducing remission in mild to moderate active ulcerative colitis in adults for whom aminosalicylate treatment is not sufficient. It is one of three brands of oral budesonide available in the UK.

Other oral budesonide products include:
- Budenofalk® is licensed for induction of remission in patients with mild to moderate active Crohn’s disease affecting the ileum and/or the ascending colon and induction of remission in patients with active collagenous colitis (two products are available; 3mg gastro-resistant capsules and 9mg gastro-resistant granules). The 3mg capsules are also licensed for induction and maintenance of remission in autoimmune hepatitis.
- Entocort® is licensed for induction of remission in patients with mild to moderate active Crohn’s disease affecting the ileum and/or the ascending colon only (3mg controlled-release capsules).

#### DETAILS OF PRODUCTS ASSESSED
Images of the Cortiment® 9mg prolonged release product and associated labels were assessed. 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.

- Two other budesonide oral products are available and therefore there is potential for confusion when prescribing and dispensing, particularly if selecting from a list of generic names on prescribing systems. This issue also applies to other medicines where different brands of the same drug are available.
- Confusion between the other oral budesonide brands is possible as the licensed indications, dose forms and dosing schedules are different e.g. Budenofalk and Entocort 3mg prescribed as 3 capsules daily whereas Cortiment® dosing is one 9mg tablet daily.
- Cortiment® is contraindicated in patients with a soya or peanut allergy, however, this does not apply to Budenofalk and Entocort.
- Ferring Pharmaceuticals packaging is blue and white throughout their range. Incorrect product selection during dispensing or by the patients who are prescribed more than one Ferring Pharmaceuticals medication is a potential risk. However, this risk also applies to other manufacturers with a corporate packaging theme.

#### POTENTIAL NEXT STEPS AND MITIGATION ACTIONS
Recommendations for local users
- Prescribing and dispensing systems (both electronic and paper-based) should be reviewed to minimise the possibility of prescribing or selecting the wrong budesonide product.
- We recommend careful counselling and advice for patients to ensure that they are aware of the dosing schedule of their medication. This is particularly important for patients previously prescribed a budesonide product for which the number of capsules/tablets taken was different.
- Prescribers need to be aware of the Cortiment® contraindication for patients with a soya or peanut allergy, particularly if switching from the other brands of budesonide for which this contraindication does not apply.

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This report was produced in October 2015 using the photographic images of Cortiment® 9mg prolonged release tablets.

This report summarises product assessments undertaken by:
Northern and Yorkshire Regional Drug and Therapeutics Centre (Newcastle) and North West Medicines
The UKMi product safety assessment group would appreciate your views on the usefulness of this report. We have devised a short survey which we would appreciate you completing, it should take approximately 10 minutes to complete. Click the following link to complete the survey: https://www.surveymonkey.com/r/UKMiProductSafetyAssessments.