

Prescribing Information: Cortiment® 9 mg, prolonged release tablets

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product(s): Cortiment® 9 mg, prolonged release tablets

Composition: One tablet contains 9 mg of budesonide.

Indication: Induction of remission in patients with mild to moderate active Ulcerative Colitis where 5-ASA treatment is not sufficient and induction of remission in patients with active Microscopic Colitis

Dosage: Adults:

The recommended daily dose for induction of remission for both Ulcerative and Microscopic Colitis is one 9 mg tablet in the morning, for up to 8 weeks. When treatment is discontinued, it may be useful to gradually reduce the dose.

Children: No data are available, therefore the use in paediatric population is not recommended until further data become available.

Contraindications: Hypersensitivity to the active substance, soya oil, peanut oil or to any of the excipients of the product.

Special Warnings and Precautions: Caution is recommended in patients with infections, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts or with a family history of diabetes or glaucoma or with any other condition where the use of glucocorticoids may have unwanted effects. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare condition diseases such as Central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Reduced liver function may affect the elimination of glucocorticoids including budesonide, causing higher systemic exposure. Treatment with Cortiment tablets results in

lower systemic steroid levels than conventional oral glucocorticoid therapy. As corticosteroids are known to have immunological effects the co-administration of Cortiment tablets is likely to reduce the immune response to vaccines.

Concomitant administration of ketoconazole or other potent CYP3A4 inhibitors should be avoided.

Pregnancy: Cortiment should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus.

Side effects: For the full list of side effects please consult the Summary of Product Characteristics.

Common: nausea, abdominal pain upper, abdominal distension, abdominal pain, dry mouth, dyspepsia, headache, insomnia, acne, fatigue, myalgia, blood cortisol decreased.

Uncommon: Flatulence, dizziness, mood altered, oedema peripheral, back pain, muscle spasms, influenza, leukocytosis.

Nature and Contents of Container: The tablets are packaged in blister packs with aluminium push through foil, contained in a cardboard carton.

Marketing Authorisation Number: Tablets 9 mg: 03194/0113

Marketing Authorisation Holder: Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, United Kingdom.

Legal Category: POM.

Basic NHS Price: £75.00 for 30 x 9 mg tablets.

Date of Preparation of Prescribing Information: January 2021. Cortiment is a registered trademark.

UK-COR-2100001: January 2021.

Adverse events should be reported.

Reporting forms and information

can be found at

www.mhra.gov.uk/yellowcard.

Adverse events should also be reported

to Ferring Pharmaceuticals Ltd.

Tel: 0800 111 4126.

Email: medical.uk@ferring.com