REAL WORLD EVIDENCE
DEMONSTRATES CORTIMENT IS AN EFFECTIVE ADD-ON THERAPY WITH A LOW SIDE EFFECT PROFILE FOR ACTIVE MILD TO MODERATE UC FLARES[3-6]

CORTIMENT®
budesonide

9 mg tablet once-daily for up to 8 weeks

SYSTEMIC STEROIDS ARE OVERUSED[3,4]

14% of IBD patients exposed to systemic steroids experienced steroid excess according to a national audit*[3]

In a local audit involving two hospital trusts, the percentage of IBD patients exposed to steroid excess was 21% and even higher in UC patients (27%).[4]

Long-term systemic steroid use is associated with a wide range of side effects including diabetes, osteoporosis and hypertension.[5,6]

Targeted topical oral steroid treatments, such as CORTIMENT, which minimise the risk of side effects and are not associated with adrenal suppression or reduction in bone mineral density, can be used as an alternative.[7]

*According to the ECCO guidelines steroid excess is defined as >2 steroid courses within the preceding 12 months or disease flare on steroid withdrawal or within 3 months of stopping steroids.[4,8]
IBD = Inflammatory bowel disease; UC = ulcerative colitis.

INTERNATIONAL REAL WORLD EVIDENCE DEMONSTRATES CORTIMENT'S EFFICACY IN FLARING MILD TO MODERATE UC PATIENTS[1,9]

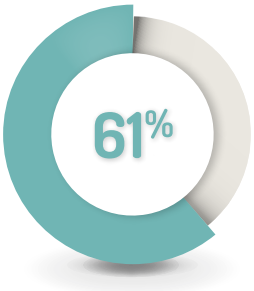
In a prospective, multi-centre, observational cohort study, CORE Practice, in which 349 patients received one 9 mg CORTIMENT tablet once-daily (OD) for the induction treatment period:

60% OF PATIENTS (n=196) ACHIEVED CLINICAL IMPROVEMENT* AT THE END OF INDUCTION TREATMENT

52% (n=169) ACHIEVED CLINICAL REMISSION† AT THE END OF INDUCTION TREATMENT

AT THE END OF INDUCTION TREATMENT, **63% OF PATIENTS' SYMPTOMS WERE RESOLVED‡** AND THE MEDIAN TIME TO SYMPTOM RESOLUTION WAS

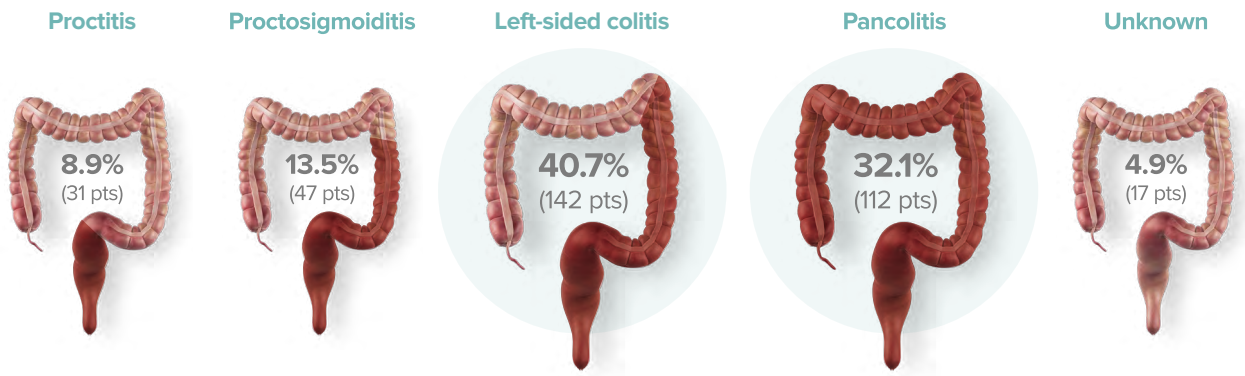
Patients are highly satisfied§ with CORTIMENT:



61% (n=214) OF PATIENTS HAD HIGH TREATMENT SATISFACTION SCORES§ AT THE END OF INDUCTION TREATMENT

*CLINICAL IMPROVEMENT was defined as a reduction of ≥ 3 points in the UCDAI clinical subscore.
†CLINICAL REMISSION was defined as ≤1 in the UCDAI subscore.
‡SYMPTOM RESOLUTION was defined as rectal bleeding of 0 and stool frequency of ≤1.
§TREATMENT SATISFACTION was defined as VAS scale score 7-10.

Distribution and extent of UC in the CORE Practice study:[1]



Cohort information (ITT population):[9]

Patient numbers	Dose schedule
59 (16.9%)	CORTIMENT added >14 days after 5-ASA optimisation for current flare
260 (74.5%)	CORTIMENT added ≤14 days from 5-ASA optimisation for current flare or without dose modification
30 (8.6%)	CORTIMENT monotherapy

UC = ulcerative colitis; ITT = intention-to-treat.

UK REAL WORLD EVIDENCE SUPPORTS THAT CORTIMENT HAS A PROFOUND REDUCTION IN THE INCIDENCE OF SIDE EFFECTS AND IMPACT ON DAILY LIFE VS. PREDNISOLONE[2]

In a 2020 observational analysis evaluating the tolerability and ease of administration of CORTIMENT 9 mg tablets, at the 6-week data review point:

	Prednisolone	CORTIMENT
% of patients who experienced ≥1 adverse events during treatment	**79%** (n=22)	**21%** (n=6)
% of patients who experienced moderate to severe impact on daily life	**46%** (n=13)	**7%** (n=2)

At **two weeks** of treatment with CORTIMENT, rectal bleeding and increased stool frequency were resolved in 32% (n=9) and 36% (n=10) of patients respectively.

Patients are happy to take CORTIMENT to treat future UC flares:

93% (n=27) OF PATIENTS FOUND HCPs INSTRUCTIONS ON TAKING CORTIMENT VERY EASY TO UNDERSTAND

OF THOSE PATIENTS EXPRESSING A PREFERENCE **7 OUT OF 10** (n=19) WOULD TAKE CORTIMENT AGAIN IF PRESCRIBED

Data from this UK Real World Evidence study supports the safety profile of CORTIMENT reported in the international Real World Evidence study (24.1% (n=84) of patients reported ≥1 adverse event).[1,2]

CORTIMENT: AN ALTERNATIVE TARGETED TOPICAL ORAL STEROID[7,10]

- BSG recommends that topically-acting oral corticosteroids such as budesonide MMX® can be used as an alternative treatment for those wishing to avoid systemic corticosteroids.[7]
- CORTIMENT does not require concurrent use of gastrointestinal and bone protection.[10]

Prescribe 1 x 9 mg CORTIMENT tablet once-daily for up to 8 weeks[10]

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

References

1. Danese S, *et al. J Crohns Colitis.* 2019;13(Suppl 1):296–297. **2.** Kearns J, *et al. J Crohns Colitis.* 2020;14(Suppl 1):S664-S665. **3.** Raine T, *et al. Gut.* 2016;7(1):A1-A310 OC-080. **4.** Data on file. Ferring UK Ltd. **5.** Prednisolone 5 mg tablets. SmPC. **6.** Danese S, *et al. Aliment Pharmacol Ther.* 2014;39:1095–1103. **7.** Lamb CA, *et al. Gut.* 2019;68(Suppl 3):s1-s106. **8.** Gomollón F, *et al. Journal of Crohn's and Colitis.* 2017:3–25. **9.** Data on file CSR. Ferring UK Ltd. **10.** Cortiment 9 mg, Prolonged Release Tablets. SmPC.

FERRING PHARMACEUTICALS

Positive UC action. Positive UC outcomes.

MAKING A tangible DIFFERENCE

Job code: UK-COR-2000022. Date of preparation: February 2021.