

Clipper 5 mg Gastro-Resistant Prolonged-Release Tablets Prescribing Information

Please refer to Summary of Product Characteristics (SPC) before prescribing.

Presentation: Each tablet contains 5mg of beclometasone dipropionate (BDP) in a gastro-resistant prolonged release formulation. **Indication:** For the treatment of mild or moderate ulcerative colitis in active phase, as add-on therapy to 5-aminosalicylic acid (5-ASA) containing drugs in patients who are non-responders to 5-ASA therapy in active phase. **Dosage and administration:** *Adults:* One 5 mg tablet a day to be taken in the morning before or after a light breakfast (swallow whole with a little liquid). Therapy cycles of not more than four weeks are recommended. *Elderly:* No special dose adjustment is recommended. However, experience in the elderly is limited. *Children:* Not recommended for use in children. **Contraindications:** Hypersensitivity to BDP or to any of the excipients; tubercular, local mycotic and viral infections. **Warnings and precautions:** Renal and hepatic insufficiency, tuberculosis, diabetes mellitus, gastro-duodenal ulcer, serious arterial hypertension, osteoporosis, hypoadrenalism, glaucoma and cataract. Not recommended in severe hepatic impairment. Start appropriate antibiotic therapy if an intestinal infection is identified before treatment initiation or if it occurs during treatment. Use of the product for longer than four weeks is not recommended. The effect on hypothalamic pituitary adrenal (HPA)–axis is considered to be transient and a recovery of HPA function is expected to occur after withdrawal of the drug. However, after the usual treatment period, careful supervision of patients' clinical symptoms is recommended. Possible adverse effects related to the suppression of HPA-axis may occur with prolonged treatment. Suppression of the HPA-axis can reduce the stress response therefore supplementary glucocorticoid treatment is recommended during surgery or other stresses. Not recommended in patients with hereditary problems of galactose intolerance or Lapp lactase deficiency or glucose-galactose malabsorption. Patients and/or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Risks may be higher with high doses/systemic exposure. Particular care is required when considering use in patients with existing or previous history of severe affective disorders in themselves or first-degree relatives. Consider referral of patients reporting blurred vision or visual disturbances to an ophthalmologist as causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy. **Interactions:** No interaction studies have been performed. Possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded and therefore caution and appropriate monitoring is advised. Clipper in clinical studies has been used in conjunction with oral or rectal treatment with mesalazine. Even if no specific pharmacodynamic interactions have been studied, clinical trials did not evidence any increase of adverse events severity due to the association of BDP with 5-ASA products. In addition, according to the different pharmacokinetic pathway of the two drugs, metabolic interactions are not expected to occur. **Fertility, pregnancy and lactation:** Clipper should not be used in pregnancy and is not recommended during lactation unless strictly indicated after a careful risk/benefit evaluation. **Effects on driving and operating machinery:** No or negligible influence on the ability to drive and use machines. **Side effects:** *Common:* irritable, euphoric, depressed and labile mood, suicidal thoughts, psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances, cognitive dysfunction including confusion and amnesia. *Uncommon:* headache, somnolence, nausea, constipation, abdominal pain, muscle cramps, menorrhagia, influenza like illness, pyrexia. *Rare:* oropharyngeal candidiasis, lymphopenia, monocytopenia, granulocytosis, adrenal suppression, cushingoid, obesity, headache, benign intracranial hypertension, cataract and glaucoma, lipohypertrophy, rosacea, osteoporosis. *Not Known:* blurred vision, hiccups, psychological effects have been reported on withdrawal of corticosteroids (refer to SPC for full list of side effects). **Legal category:** POM. **Price and Pack:** £56.56 1x30 tablets. **Marketing authorisation (MA) no:** PL 08829/0153. **MA holder:** Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK. **Date of Preparation:** Feb 2021.

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Chiesi Limited
on 0800 0092329 (UK) or PV.UK@Chiesi.com.