

# Entocort<sup>®</sup> CR

## Budesonide 3mg capsules

### ENTOCORT CR 3mg Capsules (budesonide) -

#### Prescribing Information

Please consult the Summary of Product Characteristics (SmPC) for full prescribing Information

**Presentation:** Hard gelatin capsules for oral

administration with an opaque, light grey body and an opaque, pink cap marked CIR 3mg in black radial print. Contains 3mg budesonide. **Indications:**

The induction of remission in patients with mild to moderate Crohn's disease affecting the ileum and/or the ascending colon. The induction of remission in patients with active microscopic colitis. **Dosage and administration:**

*Active Crohn's disease (Adults):* 9mg once daily in the morning for up to eight weeks. Full effect achieved in 2-4 weeks. When treatment is to be discontinued, dose should normally be reduced in final 2-4 weeks. *Active microscopic colitis (adults):* 9mg once daily in the morning. *Paediatric population:*

Not recommended. *Older people:* No special dose adjustment recommended. Swallow whole with water. Do not chew. **Contraindications:** Hypersensitivity

to the active substance or any of the excipients.

**Warnings and Precautions:** Side effects typical of corticosteroids may occur. Visual disturbances may occur. If a patient presents with symptoms such as blurred vision or other visual disturbances they should be considered for referral to an ophthalmologist for evaluation of the possible causes. Systemic effects may include glaucoma and when prescribed at high doses for prolonged periods, Cushing's syndrome, adrenal suppression, growth retardation, decreased bone mineral density and cataract. Caution in patients with infection, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts or with a family history of diabetes or glaucoma. Particular care in patients with existing or previous history of severe affective disorders in them or their first degree relatives. Caution when transferring from glucocorticoid of high systemic effect to Entocort CR. Chicken pox and measles may have a more serious course in patients on oral steroids. They may also suppress the HPA axis and reduce the stress response. Reduced liver function may increase systemic exposure. When treatment is discontinued, reduce dose over last 2-4 weeks. Concomitant use of CYP3A inhibitors, such as ketoconazole and cobicistat-containing products, is expected to increase the risk of systemic side effects and should be avoided unless the benefits outweigh the risks. Excessive grapefruit juice may increase systemic exposure and should be avoided. Patients with fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Entocort CR. Monitor height of children who use prolonged glucocorticoid

therapy for risk of growth suppression. **Interactions:**

Concomitant colestyramine may reduce Entocort CR uptake. Concomitant oestrogen and contraceptive steroids may increase effects. CYP3A4 inhibitors may increase systemic exposure. CYP3A4 inducers may reduce systemic exposure. May cause low

values in ACTH stimulation test. **Fertility, pregnancy and lactation:** Only to be used during pregnancy

when the potential benefits to the mother outweigh the risks for the foetus. May be used during breast

feeding. **Adverse reactions:** *Common:* Cushingoid features, hypokalaemia, behavioural changes

such as nervousness, insomnia, mood swings and depression, palpitations, dyspepsia, skin reactions (urticaria, exanthema), muscle cramps, menstrual disorders. *Uncommon:* anxiety, tremor, psychomotor

activity. *Rare:* aggression, glaucoma, cataract, blurred vision, ecchymosis. *Very rare:* Anaphylactic reaction,

growth retardation. Prescribers should consult the summary of product characteristics in relation to other adverse reactions. **Marketing Authorisation**

**Numbers, Package Quantities and basic NHS price:** PL 45329/0003. Packs of 100 capsules: £84.15. **Legal**

**category:** POM. **Marketing Authorisation Holder:**

Tillotts Pharma GmbH, Warmbacher Strasse 80, 79618 Rheinfelden, Germany. Date of preparation of PL:

September 2017

#### Adverse events should be reported.

Reporting forms and information can be

found at <https://yellowcard.mhra.gov.uk>.

Adverse events should also be reported to

Tillotts Pharma UK Ltd. Tel: 01522 813500.

#### References:

1. Greenberg GR *et al*. N Engl J Med 1994; 331:836-41.
2. Rezaie A *et al*. Cochrane Database Syst Rev 2015; 6:CD000296.
3. Entocort<sup>®</sup> CR 3mg Capsules – Summary of Product Characteristics.

Date of preparation: January 2018. PU-00131.



ZERIA GROUP

## TILLOTTS PHARMA

GI-health is our passion™