

Combined international Abbreviated Prescribing information for Entocort™ 3mg capsules and Entocort™ enema, tablet for rectal suspension 2 mg (0.02 mg/mL). This API has been conceived for use in material for international congresses and on international websites.

## **Entocort™**

**Active ingredient:** Budesonide.

**Composition:** Capsule: 1 modified-release capsule contains: 3 mg budesonide. Enema: One dispersible tablet contains 2.3 mg budesonide. The volume of the solution is 115 ml, thus the reconstituted rectal suspension contains 2 mg of budesonide /100 ml. Since the residual volume is about 15 ml, the dose administered to the patient is approximately 2 mg budesonide.

**Indications:** Capsules: Crohn's disease involving the ileum and/or the ascending colon. Induction of remission in patients with active microscopic colitis. Enema: Ulcerative colitis involving the rectum, the sigmoid and the descending colon.

**Posology and method of administration:** Capsules: Adults: The recommended daily dose in mild to moderate active disease is 9 mg, administered as 9 mg once daily in the morning for up to eight weeks. For long-term use, to prolong remission, the recommended dose is 6 mg, administered once daily in the morning. Microscopic colitis: 9 mg once daily for a duration of eight weeks. Children 8 years and above, with a body weight over 25 kg: The recommended daily dose in mild to moderate active disease is 9 mg, administered once daily in the morning, for up to eight weeks. Entocort™ capsules must be swallowed whole with water. Enema: Adults: One enema nightly for 4 weeks. If the patient is not in remission after 4 weeks, the treatment period may be prolonged to eight weeks. Children: Experience with the enema in children is limited.

**Contraindications:** Hypersensitivity to budesonide or any of the other ingredients.

**Precautions:** Pregnancy. Lactation. Children.

Capsules: Close medical supervision is required in the following diseases: Infections, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataract, family history of diabetes or glaucoma. Chickenpox, measles or any other condition where glucocorticosteroids may have unwanted effects. Enema: contains lactose and methyl-, propyl -parahydroxybenzoate.

**Special care:** Capsules: Before surgery or other stress situations.

Capsules/Enema: Patients with symptoms such as blurred vision or other visual disturbances. When switching from other steroids.

**Interactions:** CYP3A4 inhibitors (i.a. ketokonazol, cobicistat), estrogens, oral contraceptives, ACTH stimulation test for diagnosing pituitary insufficiency.  
Capsules: Grapefruit juice

**Side effects:** Capsules and Enema: Skin reactions (urticaria, exanthema); depression; psychomotor hyperactivity; insomnia; anxiety; aggression; cataract including subcapsular cataract; vision, blurred; ecchymosis; anaphylactic reaction.

Capsules: Cushingoid features; hypokalemia; behavioural changes such as nervousness and mood swings; palpitations; dyspepsia; muscle cramps; menstrual disorders; tremor; growth retardation.

Enema: Gastrointestinal disturbances, e.g. flatulence; nausea; diarrhea; agitation; signs or symptoms of systemic glucocorticosteroid effects, including hypofunction of the adrenal gland.

Available on prescription only.

Date of Information: 03/2017

Licence holder and supplier: Tillotts Pharma AG, Switzerland.

This abbreviated prescribing information is based on the Products' Company Core Data Sheets (both: last update 03/2017). Trade name, formulations, pack sizes, indications and dosages may vary from country to country. Before prescribing, please consult your local Summary of Product Characteristics. Detailed prescribing information is available from all suppliers of Entocort™ and Tillotts Pharma AG, Switzerland ([www.tillotts.com](http://www.tillotts.com)). Additional information is available from [medical@tillotts.com](mailto:medical@tillotts.com).

The trademark Entocort™ is registered in over 45 countries as Entocort™ and as Entocir™, Entocord™, Budecol™ and Zentacort™ in Italy, Spain, Greece and Japan, respectively. The rights to Entocort, including the rights to the trademark, are owned by Tillotts Pharma AG in various countries (transfer of market authorisations to Tillotts Pharma in process) except for the USA.

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