ENTOCORT® 3mg capsules.
ENTOCORT® enema, tablet for rectal suspension 2 mg (0.02 mg/mL).
Active ingredient: Budesonide.

Composition:
Capsules: One hard capsule with gastro-resistant pellets contains 3 mg budesonide.
Suspension: 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 about15 ml, the dose administered to the patient is approximately 2 mg budesonide.

Indications:
Capsules: Induction and maintenance of remission in mild to moderate active Crohn's disease affecting the terminal ileum and/or the ascending colon.
Suspension: Mild to moderate ulcerative colitis involving the rectum, the sigmoid and the descending colon

Posology and method of administration:
Capsules: For adults daily dose is 9 mg once daily in the morning, up to eight weeks. For maintenance of remission 6 mg once daily is recommended.
Children 8 years and older with ≥ 25kg: 9 mg once daily in the morning, up to eight weeks. Data for long-term treatment are not available.
Capsules must be swallowed whole preferably with some liquid before breakfast.
Suspension: Adults: One enema nightly for 4 weeks. If the patient is not in remission after 4 weeks, the treatment period may be prolonged to 8 weeks.
Children: Experience with the enema in children is limited.

Contraindications:
Hypersensitivity to budesonide or any of the other ingredients.
Only capsules: Severe hepatic impairment. Not for: Severe flares, Crohn's disease of the distal colon or proximal bowel or extra-intestinal manifestations.

Precautions: Pregnancy. Lactation. Children.
Local infections of the intestine, systemic infections or tuberculosis.
Only capsules: Close medical supervision is required in the following diseases: Hypertension, diabetes mellitus, osteoporosis, peptic ulcer (gastric or duodenal), glaucoma, cataract, family history of diabetes or glaucoma.
Chickenpox, herpes zoster or measles.
Only suspension: Contains the lactose and methyl- , propyl – parahydroxybenzoate.

Special care:
Only capsules: Myocardial infarct, large wounds, before surgery, bone fractures, epilepsy, psychosis, thrombophlebitis; severe hypertension; congestive heart failure; hypothyroidism, concomitant use of salicylates.
Capsules and suspension when switching from other steroids.

Interactions:
CYP3A4 inhibitors (i.a. ketokonazol), grapefruit juice, CYP3A4 inducers (i.a. rifampicin), glycosides, diuretics, antidiabetics, anticoagulants, NSAIDs, estrogens, oral contraceptives.

Adverse reactions :
Skin: Allergic exanthema, urticaria, petechiae, red striae, steroid acne, ecchymosis, delayed wound healing, contact dermatitis.
Muscle and skeleton: Muscle cramps, tremor, osteoporosis, aseptic necrosis of bone (femur and head of the humerus).
Eyes: Glaucoma, cataract, blurred vision
Central and peripheral nervous system: Depression, irritability, euphoria, restlessness, insomnia, mood changes.
Gastrointestinal tract: Dyspepsia, gastroduodenal ulcer, pancreatitis,..
Immune system: Obstruction of immune response (increased risk of infection). Anaphylactic reaction
Metabolism: Cushing's syndrome (moon-face, truncal obesity), reduced glucose tolerance, diabetes mellitus, sodium retention with oedema formation, increased excretion of potassium, inactivity and/or atrophy of the adrenal cortex, growth retardation in children, disturbance of sex hormone secretion (e.g. amenorrhoea, hirsutism, impotence).
Cardiovascular system: Hypertension, palpitations.
Vascular system: Increased risk of thrombosis, vasculitis (withdrawal syndrome after long-term therapy).
Only suspension: Flatulence, nausea, diarrhea.

For detailed information see patient leaflet or professional prescribing information.
Available on prescription only.
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Tillotts Pharma AG
Baslerstrasse 15
CH-4310 Rheinfelden, Switzerland
www.tillotts.com