Budicort® ER
Budesonide

Presentation
Budicort® ER tablet: Each extended release tablet contains budesonide BP 9 mg.

Description
Budesonide is a synthetic corticosteroid having potent glucocorticoid activity and weak mineralocorticoid activity. It has approximately 200-fold higher affinity for the glucocorticoid receptor than cortisol and 15-fold than prednisolone. Budesonide is effective against inflammatory bowel diseases. It reduces inflammation of colon and also helps heal the lining of the colon.

Indications and uses
Budesonide is a glucocorticoid indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

Dosage and Administration
One 9 mg Budicort® ER tablet should be taken once daily in the morning with or without food for up to 8 weeks or as prescribed by the doctor.

Side Effects
● headache ● nausea ● upper abdominal pain ● fatigue ● acne ● flatulence
● joint pain ● urinary tract infection ● abdominal distension ● constipation

Precautions
● Since budesonide is a glucocorticoid, general warnings concerning glucocorticoids should be followed.

● Risk of impaired adrenal function when transferring from glucocorticoid treatment with higher systemic effects to glucocorticoid treatment with lower systemic effects, such as budesonide. Taper patients slowly from systemic corticosteroids if transferring to budesonide.

● Potential worsening of infections (e.g., chickenpox, measles, existing tuberculosis, fungal, bacterial, viral, or parasitic infection). Use with caution in patients with these infections.

● Reduced liver function affects the elimination of glucocorticoid, and increases systemic availability of oral budesonide.

Caution should be taken in patients with
● hypertension ● diabetes mellitus ● osteoporosis ● peptic ulcer ● glaucoma or cataracts
● having a family history of diabetes, cataract or glaucoma

Use in pregnancy and lactation
Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Budesonide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers
Budesonide is secreted in human milk. So, a decision should be made whether to discontinue nursing or budesonide taking into account the clinical importance of the drug to the mother.

Use in children
Safety and effectiveness of budesonide in pediatric patients have not been established.

Use in Hepatic Impaired patients
Monitor patients for signs and/or symptoms of hypercorticism.

Contraindications
Known hypersensitivity to budesonide or any of the ingredients in Budicort® ER tablets.

Drug interactions
Avoid Cytochrome P450 3A4 inhibitors (e.g. ketoconazole, grapefruit juice). It may cause increased systemic corticosteroid effects. Budesonide does not affect the plasma levels of oral contraceptives.

Overdosage
If glucocorticoids are used at excessive doses for prolonged periods, systemic glucocorticoid effects such as hypercorticism and adrenal suppression may occur.

Storage
Budesonide extended release tablets should be stored below 30°C. Store in a cool and dry place protected from light and moisture.

Commercial pack
Budicort® ER: Each box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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