

BALACOL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for Balacol (Balsalazide Disodium 750 mg Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Balsalazide disodium dihydrate is a pro-drug of mesalamine which blocks production of arachidonic acid metabolites in the colon.

INDICATION: Balacol is indicated for the treatment of mild to moderate ulcerative colitis and maintenance of remission.

DOSAGE AND ADMINISTRATION: To be swallowed whole with or after food. *For Adults:* 2.25g Balsalazide disodium (3 capsules) three times daily (6.75g daily) until remission or for 12 weeks maximum. Rectal or oral steroids can be given concomitantly if necessary. *Maintenance treatment:* The recommended starting dose is 1.5g Balsalazide disodium (2 capsules) twice daily (3g daily). The dose can be adjusted based on each patient's response; there may be an additional benefit with a dose up to 6g daily. *For Elderly:* No dose adjustment is anticipated. *For Children:* Balsalazide capsules is not recommended in children

CONTRAINDICATION: It is contraindicated in patients with severe hepatic impairment, moderate-severe renal impairment. In pregnant and breast feeding women. In patients with hypersensitivity to any component of the product or its metabolites, including mesalazine. History of hypersensitivity to salicylates. Hypersensitivity reactions may include, but are not limited to the following: anaphylaxis, bronchospasm, and skin reaction.

WARNINGS & PRECAUTIONS: Balsalazide capsules should be used with caution in patients with asthma, bleeding disorders, active ulcer disease, mild renal impairment, ulcerative colitis, pyloric stenosis or those with established hepatic disease. During its treatment blood counts, BUN/creatinine and urine analysis should be performed. Patients receiving balsalazide should be advised to report any unexplained bleeding, bruising, purpura, sore throat, fever or malaise that occurs during treatment. A blood count should be performed and the drug stopped immediately if there is suspicion of a blood dyscrasia. Patients with pyloric stenosis may have prolonged gastric retention of Balsalazide capsules. Exacerbations of Ulcerative Colitis may be occurred.

DRUG INTERACTION: It can interact with methotrexate, mesalazine, N-acetylmessalazine, digoxin, azathioprine or 6-mercaptopurine.

ADVERSE REACTIONS: Fatigue, fever, flu-like disorder, dry mouth, aplastic anaemia, leucopenia, neutropenia, agranulocytosis, thrombocytopenia, neuropathy, myocarditis, pericarditis, bronchospasm, coughing, abdominal pain, diarrhoea, nausea, vomiting, aggravation of ulcerative colitis, acute pancreatitis, flatulence, dyspepsia, anorexia, constipation, hepatitis, cholelithiasis, rash, systemic lupus erythematosus-like syndrome, arthralgia, interstitial nephritis, urinary tract infection and hypersensitivity. The adverse effects are expected to be those of mesalazine.

MARKETED BY:



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(Additional information is available on request)