

## COOLGUT

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

Abbreviated prescribing information for Coolgut Tablets (Mesalazine Prolonged Release Tablets I.P. 1.2g) [Please refer the complete prescribing information for details]]

**PHARMACOLOGICAL PROPERTIES:** Mesalazine is an anti-inflammatory agent.

**INDICATION:** Mesalazine tablets are indicated for the patients with ulcerative colitis.

**DOSAGE AND ADMINISTRATION:** Two to four tablets should be taken once daily with meal.

**CONTRAINDICATION:** It is contraindicated in the patients with known hypersensitivity to mesalazine, salicylates or any of the ingredients of the tablet.

**WARNINGS & PRECAUTIONS:** Renal dysfunction and renal disease patients should have evaluation of renal functions prior to initiation of mesalazine therapy or should evaluate on periodic basis, photosensitivity patients with pre-existing skin conditions such as atopic dermatitis and atopic eczema have reported more severe photosensitivity reactions, Mesalazine treatment is associated with an acute intolerance syndrome. Caution should be taken while administering the mesalazine in the patients with liver disease. Upper GI tract obstruction may delay the release of mesalazine. It may elevate the test results of urinary normetanephrine by liquid chromatography.

**DRUG INTERACTION:** Concurrent use of nephrotoxic agents and non-steroidal anti-inflammatory drugs (NSAIDs) may increase the risk of renal reactions. Blood disorder may be potentiated while concomitant use of azathioprine or 6-mercaptopurine.

**ADVERSE REACTIONS:** Colitis flare, dizziness, nausea, joint pain, rash, lethargy and constipation, dry mouth, malaise, lower back discomfort, mild disorientation, mild indigestion and cramping; headache, aching, vomiting, photosensitivity reaction, muscle cramps, a stuffy head, plugged ears, fever, pharyngitis, rhinitis, dyspepsia, hypertonia, flatulence, dysmenorrhea, chest pain, chills, flu syndrome, peripheral edema, myalgia, colitis exacerbation, increased cough, arthritis, insomnia, decreased libido, rheumatoid arthritis, stomatitis, gastrointestinal hemorrhage, infection, joint disorder, migraine, nervousness, rectal disorder, rectal hemorrhage, tenesmus, urinary frequency, flatulence. Tachycardia, hypertension, hepatotoxicity, leukopenia, arthralgia, depression, confusion, pneumonia, Stevens-Johnson syndrome, DRESS, tinnitus and conjunctivitis, interstitial nephritis and elevated laboratory values.

### MARKETED BY:



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(Additional information is available on request)