Cozycol™ 800

Mesalamine USP 800 mg

Composition
Each delayed release tablet contains Mesalamine (5-AminoSalicylic Acid or Mesalazine) USP 800 mg.

Pharmacology
The mechanism of action of Mesalamine is unknown, but appears to be topical rather than systemic. Mucosal production of Arachidonic Acid metabolites, both through the cyclooxygenase pathways, that is, prostanoids, and through the lipoxygenase pathways, that is, leukotrienes and hydroxyeicosatetraenoic acids, is increased in patients with chronic inflammatory bowel disease. Mesalamine diminishes inflammation by blocking cyclooxygenase and inhibiting prostaglandin production in the colon.

Indication
Cozycol™ is indicated for
- Treatment of mild to moderately active Ulcerative Colitis
- Maintenance of remission of Ulcerative Colitis
- Maintenance of remission of Crohn's disease

Dosage and administration
Acute disease: 3-6 delayed release tablets (2400-4800 mg) daily in divided doses for 6 (six) weeks.
Maintenance therapy: The recommended dosage is 3 delayed release tablets (2400 mg) daily in divided doses.
Maintenance of remission of Crohn's disease: 3 delayed release tablets (2400 mg) daily in divided doses.
Paediatric : Safety and effectiveness has not been established.
Elderly: Because elderly patients are more likely to have decreased renal function, care should be taken when prescribing this drug therapy. It is recommended that all patients have an evaluation of renal function prior to initiation of Mesalamine tablets. Monitor blood cell counts during drug therapy.

Contraindication
Hypersensitivity to salicylates or to any other component of the formulation .

Warning and Precaution
Patients with pyloric stenosis may have prolonged gastric retention of Mesalamine tablets which could delay release of Mesalamine in the colon.

Renal impairment, including minimal change nephropathy and acute and chronic interstitial nephritis has been reported in patients taking Mesalamine. Therefore, caution should be exercised when using Mesalamine in patients with known renal dysfunction or history of renal disease. Patients should have renal function monitored , prior to treatment start and then it should be monitored periodically during treatment. There have been reports of hepatic failure in patients with pre-existing liver disease who have been administered Mesalamine. Caution should be exercised when administering Mesalamine to patients with liver impairment.

Use in Special Population
Pregnant women: It should be given in pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactating mother: Caution is advised when it is administered to a nursing mother.
Geriatrics: Patients who are 65 years or older, caution should be taken to closely monitor blood cell counts during Mesalamine therapy.

Drug Interaction
Concurrent use of other known nephrotoxic agents such as NSAIDs and Azathioprine may increase the risk of renal reactions.

Side effect
The commonly reported adverse events are headache, nausea, dizziness, asthenia, dyspepsia, vomiting, pruritus etc.

Overdose
There is no specific antidote for Mesalamine overdose. Treatment for suspected acute severe toxicity should be symptomatic and supportive. This may include prevention of further gastrointestinal tract absorption, correction of fluid electrolyte imbalance and maintenance of adequate renal function. This is a pH dependent delayed-release product and this factor should be considered when treating a suspected over dose.

Storage
Store below 30°C. Protect from light and moisture. Keep all medicines out of the reach of children.

How Supplied
Each Box contains 30 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh