FIRST TIME GENERIC APPROVAL

Brand Name	Apriso™
Generic Name	mesalamine
Drug Manufacturer	Sun Pharmaceutical Industries, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

May 11, 2022

LAUNCH DATE

May 17, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 214585

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Mesalamine extended-release capsules are indicated for the induction of remission and for the treatment of adult patients with mildly to moderately active ulcerative colitis.

MECHANISMS OF ACTION

The mechanism of action of mesalamine (and sulfasalazine) is not fully understood, but it appears to be a topical anti-inflammatory effect on colonic epithelial cells. Mucosal production of arachidonic acid (AA) metabolites, both through the cyclooxygenase pathways (i.e., prostanoids) and through the lipoxygenase pathways (i.e., leukotrienes (LTs)) and hydroxyeicosatetraenoic acids (HETEs), is increased in patients with ulcerative colitis, and it is possible that mesalamine diminishes inflammation by blocking cyclooxygenase and inhibiting prostaglandin (PG) production in the colon.

DOSE FORM AND STRENGTH

Mesalamine 500mg extended-release capsules

DOSE & ADMINISTRATION

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The recommended dosage for the induction of remission and the symptomatic treatment of mildly to moderately active ulcerative colitis in adults is 1 g (2 mesalamine extended-release 500-mg capsules) 4 times a day for a total daily dosage of 4 g. Treatment duration in controlled trials was up to 8 weeks.