

Public Summary

Summary for ARTG Entry: 14486 SALAZOPYRIN sulfasalazine 500mg tablet bottle

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
 Australia
ARTG Start Date 5/09/1991
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products**1. Salazopyrin sulfasalazine 500mg tablet**

Product Type	Single Medicine Product	Effective date	20/05/2016
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Ulcerative Colitis and Crohn's Disease: Adjunct in the treatment of ulcerative colitis with the usual supportive and dietary measures. For the management of severe, acute attacks of ulcerative colitis, rectal and systemic corticosteroid therapy appears to be clinically superior to sulfasalazine, but sulfasalazine may be more effective than corticosteroids in reducing the number of relapses in patients on maintenance therapy. In the treatment of active Crohn's disease, especially in patients with colonic involvement. Rheumatoid Arthritis: Salazopyrin EN-tabs are indicated for rheumatoid arthritis which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	5 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information**Pack Size**

100 tablets

Components**1. Medicine Component****Dosage Form****Route of Administration****Visual Identification****Active Ingredients**

Sulfasalazine

Poison Schedule

(S4) Prescription Only Medicine

Tablet, uncoated

Oral

Yellow-orange, round, scored tablets marked with 'KPh' on one side and '101' on the other side

500 mg

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