AUSTRALIAN PRODUCT INFORMATION

SALOFALK® Enemas (mesalazine)

1. NAME OF THE MEDICINE

SALOFALK Enemas mesalazine 2 g/60 mL or 4 g/60 mL

Mesalazine.

2 . QUALITATIVE AND QUANTITATIVE COMPOSITION

SALOFALK enemas contain either 2 g/60 mL or 4 g/60 mL mesalazine as the active ingredient.

Excipients with known effect: sulphites and benzoates

See section 4.4 Special warnings and precautions for use.

For the full list of excipients, see section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

SALOFALK 2 g/ 60 mL and 4 g/60 mL enemas are presented as a very light tan to brown, homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

SALOFALK enemas are indicated in the treatment of acute ulcerative colitis of mild to moderate severity and for the maintenance treatment of ulcerative colitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

Unless otherwise advised, a dose of 2 g or 4 g mesalazine as SALOFALK enema once a day is used for the treatment of acute ulcerative colitis or for the maintenance of remission.

The content of one enema bottle (2 g/60 mL, or 4 g/60 mL) is instilled in the rectum once every evening prior to going to bed.

The best results are achieved if the bowels are evacuated prior to instillation of SALOFALK enema.

The action of SALOFALK enemas is enhanced if the patient lies on the left side when introducing the enema after the insertion of the applicator, which is lubricated for patient comfort. The concertina design of the bottle helps the patient to administer the enema. The dosage should be adjusted to suit the progress of the condition.

Discontinuation of treatment should be under supervision of the physician. Due to the considerable variation in the severity of the ulcerative colitis and the extent of the affected area it is not possible to recommend a uniform dose of mesalazine which will provide optimal effects. In clinical trials, rectal doses of 2-4 g mesalazine/day as enemas have been used in

the therapy of both acute ulcerative colitis and maintenance of remission.

Use in children
SALOFALK enemas should not be used in children 12 years old and under, as there is little experience with this age group.

4.3 CONTRAINDICATIONS

SALOFALK enema is contraindicated in patients with the following:

- hypersensitivity to salicylic acid, salicylic acid derivatives, e.g. mesalazine/5-ASA, sulfites and benzoates or to any of the other ingredients
- severe impairment of hepatic and renal function

SALOFALK enemas should be used with caution in patients with bronchial asthma. They contain sulfite which may cause hypersensitivity reactions.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

SALOFALK enemas should be given/used under medical supervision.

Use in pulmonary function impairment
Mesalazine should be used/given with caution in patients with pulmonary function impairment, particularly asthma and in patients with known hypersensitivity to sulfasalazine containing preparations. Treatment in the latter patients should be instituted with careful medical supervision. Treatment should be discontinued immediately if symptoms of acute intolerance, e.g. cramps, acute abdominal pain, fever, severe headache and skin rash, occur.

Use in hepatic impairment
Caution is recommended in patients with impaired hepatic function. SALOFALK enemas are contraindicated in patients with severe hepatic impairment (see Section 4.3 (Contraindications).

As mesalazine might cause hepatic impairment due to hypersensitivity reactions, blood parameters, like blood counts and liver function and cholestasis parameters (e.g. ALT, AST, alkaline phosphatase, γGT) may be monitored like the renal parameters.

Blood dyscrasia
Serious blood dyscrasias have been reported very rarely with mesalazine. Haematological investigations should be performed if patients suffer from unexplained haemorrhages, bruises, purpura, anaemia, fever or pharyngolaryngeal pain. SALOFALK enemas should be discontinued in case of suspected or confirmed blood dyscrasia.

Epigastric pain
Epigastric pain, also commonly associated with inflammatory bowel disease and prednisone or sulfasalazine therapy, should be investigated in order to exclude conditions such as pericarditis, hepatitis and pancreatitis either as adverse drug reactions to 5-ASA or secondary manifestations of inflammatory bowel disease. Cardiac hypersensitivity reactions (myocarditis, and pericarditis) induced by mesalazine have been rarely reported. SALOFALK enemas should then be discontinued immediately if any of these reactions occur.

Use in renal impairment
Mesalazine is not recommended in patients with impaired renal function. The blood and renal status should be determined prior to and during treatment, at the discretion of the treating

physician. As a guideline, checks are recommended 14 days after commencement of treatment, then a further 2 to 3 times at 4-weekly intervals. If the findings are normal, follow-up tests should be conducted every three months or immediately if additional signs of the disorder occur. To check renal function, it is recommended that levels of serum urea (BUN) and creatinine be determined as well as performing a urine sediment test. Mesalazine-induced renal toxicity should be considered if renal function deteriorates during treatment. If this is the case, SALOFALK enemas should be discontinued immediately.

Nephrolithiasis
Cases of nephrolithiasis have been reported with the use of mesalazine, including stones with mesalazine content. Ensure adequate fluid intake during treatment.

Severe cutaneous adverse reactions
Severe cutaneous adverse reaction (SCARs), including drug reaction with eosinophilia and systemic symptoms (DRESS), Steven-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment. Mesalazine should be discontinued, at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Idiopathic intracranial hypertension
Idiopathic intracranial hypertension (pseudotumor cerebri) has been reported in patients receiving mesalazine. Patients should be warned for signs and symptoms of idiopathic intracranial hypertension, including severe or recurrent headache, visual disturbances or tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered.

Urine discoloration
Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach (e.g. in toilets cleaned with sodium hypochlorite contained in certain bleaches).

Use in the elderly
Specific clinical data in only elderly patients for mesalazine are not available but mesalazine has been used in patients up to 75 years of age in clinical trials.

Paediatric use

SALOFALK enemas should not be used in children 12 years old and under, as there is little experience with this age group.

Effects on laboratory tests
Not known to interfere with laboratory tests or physical diagnostic agents.

Excipients with known effect

SALOFALK enemas contain potassium metabisulphite, which can induce allergic reactions, including anaphylactic symptoms and bronchial constriction (bronchospasm) in sensitive patients, particularly in those with asthma or a history of allergies.

SALOFALK enemas 2g/60 mL and 4g/60mL contain 60 mg sodium benzoate. Sodium benzoate may provoke hypersensitivity reactions in suitably predisposed patients in the form of irritation of the skin, eyes and mucous membranes.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Studies to evaluate the potential interaction between SALOFALK enemas and other drugs have not been performed. In common with other salicylates, interactions may occur during

concomitant administration of mesalazine and the following drugs:

•Coumarin-type anticoagulants:	possible potentiation of the anticoagulant effect action (increasing the risk of gastrointestinal haemorrhage)
• Glucocorticoids	possible increase in undesirable gastric effects
• Sulphonylureas:	possible increase in the blood glucose-lowering effects
• Methotrexate:	possible increase in toxic potential of methotrexate
• Probenecid/sulphinpyrazone:	possible attenuation of the uricosuric effects
• Spironolactone/frusemide:	possible attenuation of the diuretic effects
• Rifampicin	possible attenuation of the tuberculostatic effects

There is weak evidence that mesalazine might decrease the anticoagulant effect of warfarin.

In patients who are concomitantly treated with azathioprine, 6-mercaptopurine or thioguanine, possible enhanced myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine should be taken into account.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility
Fertility and reproductive performance were not impaired in rats treated orally with mesalazine prior to and during mating (both sexes) and throughout gestation and lactation (females) at doses up to 320 mg/kg/day, which is less than the maximal recommended clinical dose of SALOFALK enemas on a body surface area basis.

Use in pregnancy
(**Category C)**
There was no evidence of embryotoxicity or teratogenicity in rats and rabbits treated orally with mesalazine during the period of organogenesis at respective doses of up to 320 and 495 mg/kg/day, representing less than, and about twice, the maximal recommended clinical dose of SALOFALK enemas on a body surface area basis. Oral mesalazine does not show direct or indirect harmful effects with respect to parturition or postnatal development in animals.

Human data on use during pregnancy are limited. No adverse effect of mesalazine on pregnancy or on the health of the foetus/newborn child was shown. To date no other relevant epidemiologic data are available. In one single case after oral use of 2-4 g mesalazine per day during the 3rd and 5th months of pregnancy, renal failure in a neonate was reported.

SALOFALK enemas should only be used during pregnancy if the potential benefit outweighs the possible risk.

Use in lactation
In rats, there were no adverse effects on dams or offspring from oral administration of mesalazine during late gestation and throughout lactation at doses up to 320 mg/kg/day, which is less than the maximal recommended clinical dose of SALOFALK enemas on a body surface area basis.

There has been a report of a patient receiving mesalazine suppositories during the lactation period. Twelve hours after the initial dose, the infant developed watery diarrhoea that disappeared on discontinuation of the mesalazine therapy but reappeared on rechallenge. There have been reports of mesalazine and of its metabolite N-acetyl-5-ASA found in breast

milk. But, there is no experience with SALOFALK enemas in lactating women. SALOFALK enemas should not be used during lactation unless the likely benefit of treatment outweighs the potential hazard.
If the infant develops diarrhoea, the treatment should be temporarily discontinued and further medical advice sought.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Mesalazine is not expected to affect the ability of patients to drive or operate machinery.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

The most common adverse events seen in the clinical studies for SALOFALK enemas are headache, hair loss, abdominal pain, diarrhoea and rash. In a randomized, double-blind placebo controlled clinical trial of SALOFALK 4g/60 ml enemas in a total of 153 patients, adverse events occurred in 25% and 40% of patients in the SALOFALK enemas and placebo enema groups respectively. Events reported in at least 2 patients in this trial are shown in Table I below.

Table I

System/reaction	SALOFALK 4g/60mL enema Group (n=76)	Placebo Group (n=77)
Body as a whole-General disorders		
Headache	11.8%	7.8%
Cold	1.3%	9.1%
Fatigue	2.6%	6.5%
Hair loss	2.6%	0%
Gastrointestinal		
Nausea	0%	6.5%
Bloating	2.6%	2.6%
Constipation	1.3%	2.6%
Diarrhoea	2.6%	1.3%
Cramps	1.3%	3.9%
Skin and appendages disorder		
Rash	2.6%	5.2%
Cardiovascular		
Dizziness	0%	2.6%
Genitourinary		
Urinary tract infection	0%	2.6%
Psychiatric		
Insomnia	1.3%	2.6%

The following adverse events presented by body system have been reported in international post marketing surveillance of all SALOFALK preparations including SALOFALK enemas. In many cases, the relationship to SALOFALK treatment has not been established.

The **common: (≥1% - <10%)** adverse events were as follows:

Body as a whole – General disorders
Headache

Gastrointestinal system disorders
Abdominal pain, diarrhoea, nausea and vomiting, flatulence, exacerbation of ulcerative colitis
Skin and appendages disorder
Rash including pruritus, urticarial

The following additional adverse events were classified as **uncommon being reported in <1% of patients:**

Body as a whole – General disorders
Fever, allergic reaction

Central and peripheral nervous systems disorders
Dizziness, paraesthesia, peripheral neuropathy

Collagen disorders
Lupus erythematosus syndrome (as observed for preparations with a similar chemical structure).

Gastrointestinal system disorders
Acute pancreatitis, pancolitis, neonate diarrhoea

Liver and biliary system disorders
Hepatitis, increased liver enzyme values (transaminase activity), intrahepatic cholestasis, increased bilirubin, changes in pancreatic enzymes (lipase and amylase increased), eosinophil count increased

Musculo-skeletal system disorders
Arthralgia, myalgia, myositis

Myo-, endo-, pericardial and valve disorders
Pericarditis, myocarditis, pericardial effusion

Platelet, bleeding and clotting
Thrombocytopenia

Red blood cell disorders
Aplastic anaemia, haemolytic anaemia

Reproductive system disorders
Oligospermia (reversible)

Respiratory, thoracic and mediastinal disorders
Allergic and fibrotic lung reactions, dyspnoea, cough, bronchospasm, pleural effusion, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis

(In isolated cases hypersensitivity reactions, principally in the form of respiratory problems, may be experienced by non-asthmatics due to the content of potassium bisulfite in enemas.)

Skin and appendages disorders
Alopecia, allergic exanthema, increased sweating

Urinary system disorders
Acute or chronic interstitial nephritis, renal insufficiency, renal failure, nephrotoxicity

White cell and RES disorders
Agranulocytosis, leukopenia, neutropenia, pancytopenia

The following additional adverse events were classified as **rare being reported in < 0.1% of patients:**

Skin and appendages disorders
Photosensitivity
(More severe reactions are reported in patients with pre-existing skin conditions such as atopic dermatitis and atopic eczema)

The following additional adverse events were classified as **very rare being reported in < 0.01% of patients:**

Liver and biliary system disorders
Cholestatic hepatitis

The frequency of the following adverse events is **not** known (i.e. cannot be estimated from the available data)**:**

Urinary System Disorders
Nephrolithiasis (see section 4.4 Special Warnings and Precautions for Use for further information).

Skin and subcutaneous tissue disorders SOC
Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson-syndrome (SJS), toxic epidermal necrolysis (TEN)

Severe cutaneous adverse reactions (SCARs), including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment (see section 4.4).

Nervous system disorders
Idiopathic intracranial hypertension (see section 4.4)

4.9 OVERDOSE

There are limited data on overdosage (e.g. intended suicide with high oral doses of mesalazine), which do not indicate renal or hepatic toxicity.

Possible symptoms may include nausea, vomiting and diarrhoea, and symptoms similar to salicylate overdose.

There is no specific antidote. General supportive and symptomatic measures are recommended.

For information on the management of overdosage, contact the Poisons Information Centre on 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action
Mesalazine has been identified as the active component of sulfasalazine in inflammatory bowel disease and is thought to have a topical action. The mechanism of action by which mesalazine protects the mucosa in chronic inflammatory bowel disease is not yet fully known.

Mesalazine seems to act in multiple ways against several inflammatory mediators and principles. The results of *in vitro* investigations indicate that inhibition of lipoxygenase may play a role. Effects on prostaglandin concentrations in the intestinal mucosa have also been demonstrated, as has an influence on leukotriene production. Mesalazine may also function as a radical scavenger of reactive oxygen compounds.

Clinical trials
The criteria used to evaluate the efficacy of the substance in the therapy of ulcerative colitis are frequency of bowel movements, rectal haemorrhage, mucosal appearance on endoscopy, and severity of the disease as evaluated by a physician. These criteria are included in the Disease Activity Index (DAI) used to evaluate the efficacy of treatments for ulcerative colitis (UC).

In a multi-centre, randomised, double-blind, placebo-controlled study involving 153 patients, the efficacy of SALOFALK 4g/60 mL enemas in the therapy of ulcerative colitis was significantly better than that of placebo at 6 weeks. The study showed an endoscopic improvement of 70% vs. 37% of placebo (p=0.001). It also showed a 63% improvement by the physician global assessment (PGA) in the mesalazine group vs. 29% in the placebo group (p<0.001) while evaluation by the DAI showed a 55% decline (7.42 to 3.37) in the 5-ASA group vs. 22% (7.7 to 5.83) in the placebo group (p=0.0001). All components of the DAI were significantly lower for the treatment group than the placebo group, see table below.

Primary Efficacy Criteria, SALOFALK 4g/60 mL Enemas Vs Placebo

Efficacy Parameter	Treatment group	Mean Observation				Change from Baseline to Endpoint
		Baseline	Day 22	Day 43	Endpoint	
Overall Disease Activity Index	Mesalazine Placebo	7.42 7.70	4.05** 6.03	2.67*** 5.07	3.37*** 5.83	-55.07%+*** -21.53%
a) Stool Frequency Index	Mesalazine Placebo	1.53 1.92	1.11* 1.47	0.94* 1.31	1.01** 1.50	-0.57 -0.41
b) Rectal Bleeding Index	Mesalazine Placebo	1.82 1.73	0.59*** 1.21	0.34*** 0.87	0.51*** 1.11	-1.30*** -0.61
c) Mucosal Appearance Index	Mesalazine Placebo	2.17 2.13	1.22** 1.74	0.79*** 1.44	0.96*** 1.61	-1.21*** -0.56
d) Physician Assessment of Disease Severity	Mesalazine Placebo	1.86 1.87	1.13*** 1.62	0.70*** 1.39	0.88*** 1.55	-0.97*** -0.30

\+ Percent change for overall DAI only
* Significant mesalazine / Placebo difference, p<0.05
** Significant mesalazine / Placebo difference, p<0.01
*** Significant mesalazine / Placebo difference, p<0.001

On completing the above study, all patients were randomised to receive SALOFALK 4 g/60 mL or 2 g/60 mL enemas, once daily in an open label maintenance study. After 6 months of treatment, the DAI score improved by 62-75 % from baseline and there was no significant difference in the degree of improvement between the groups. A dose-dependent relationship with SALOFALK enemas does not seem to be evident in the maintenance of remission.

5.2 PHARMACOKINETIC PROPERTIES

General considerations
The efficacy of mesalazine (5-ASA) appears to be determined not by the systemic but the local availability of the substance at the target site.

There is little pharmacokinetic data available for rectal administered mesalazine in children. There is no pharmacokinetic data in the elderly using SALOFALK enemas.

Absorption
The systemic absorption of mesalazine decreases in the intestinal tract from the proximal to distal segments. Because of low systemic absorption rates from oral delayed release preparations or rectal applications forms of mesalazine, the main elimination route is via faeces.

Distribution
The plasma protein binding of mesalazine and acetylated mesalazine is 43% and 78%, respectively.

Metabolism
Metabolism of mesalazine occurs mainly in the intestinal mucosa and, to a lesser extent, in the liver. The main metabolite is N-acetyl-5-aminosalicylic acid, which is similar to mesalazine, is predominantly eliminated by the renal and faecal routes. It appears to have no therapeutic activity or specific toxic effects. The acetylation step appears irreversible. As metabolism occurs mainly in the intestinal mucosa, it has not been possible to differentiate between a rapid and slow acetylation form as in the case of sulfasalazine/sulfapyridine.

Excretion
Systemically absorbed mesalazine and N-acetyl-5-ASA are eliminated mainly via kidneys. Biliary excretion is a minor route of elimination.

SALOFALK enemas
4 g/60 mL enema in patients with ulcerative colitis in remission show a median C_{max} value of 0.92 µg/mL for 5-ASA at t_{max} of 11 hours, and for N-acetyl-5-ASA a median C_{max} of 1.62 µg/mL at a t_{max} of 12 hours. The median urinary recovery was 13% during the 45 hour observational period, indicating a low absorption.

The administration of high doses of mesalazine enema (2 x SALOFALK 4 g/60 mL enemas daily) in patients with severely active ulcerative colitis, administered into the caecum, showed the following C_{max} values in plasma for 5-ASA at t_{max} of 1.5 h and for N-acetyl-5-ASA at t_{max} of 2.8 h.

Application Day	Mesalazine [µg/mL]	N-acetyl-5-ASA [µg/mL]
1	1.4	1.9
2	2.5	3.6

Total urinary recovery on day 1 was 10.5% and on day 3 (steady state) 18.6% with 22% of that being mesalazine, demonstrating a low absorption rate, similar to the oral administration of SALOFALK granules. The serum elimination half-life on day 1 was 4.2h, also comparable with that of the SALOFALK granules (4.4h).

In children with ulcerative colitis, SALOFALK enemas showed the following steady state plasma concentrations:

SALOFALK enema	5-ASA [µg/mL]	Ac-5-ASA [µg/mL]
2 g/30 mL	0.2 - 1.0	0.4 - 2.0
4 g/60 mL	0.5 - 2.8	0.9 - 4.1

Scintigraphic evaluation of (^{99}Tc) technetium-sulphur colloid-labelled SALOFALK 2g /30 mL and SALOFALK 4 g/60 mL enema showed the following distribution in patients with mild to moderate active ulcerative colitis at the beginning of therapy (time: 0 week) and at time of remission after 12 weeks of treatment (median and range):

Distribution Region	SALOFALK 2 g/30 mL enemas		SALOFALK 4 g/60 mL enemas	
	0 week [%]	12 week [%]	0 week [%]	12 week [%]
Rectum	1 (0-76)	0 (0-21)	9 (0-77)	3 (0-51)
Sigmoid	99 (13-100)	100 (51-100)	61 (23-100)	85 (47-100)
Descending colon	0 (0-47)	0 (0-35)	13 (0-68)	0 (0-51)
Transverse colon	0 (0-39)	0 (0-5)	0 (0-0)	0 (0-0)
Ascending colon	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)

5.3 PRECLINICAL SAFETY DATA

Genotoxicity
There was no evidence of genotoxic potential with mesalazine in bacterial gene mutation assays, of chromosomal damage in mouse haematopoietic cells following a single oral dose, or of increases in sister chromatid exchange frequencies in Chinese hamster bone marrow following a single intraperitoneal dose.

There is growing information that 5-ASA/mesalazine protects patients with ulcerative colitis from colo-rectal cancer.

Carcinogenicity
There was no evidence of carcinogenicity in rats treated with mesalazine in the diet for 127 weeks at doses up to 320 mg/kg/day, associated with plasma concentrations of mesalazine and N-acetyl-5-ASA of 1- and 6-fold the respective clinical plasma concentrations associated with a 1500 mg dose of the granules and SALOFALK 4 g/60mL enemas.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

SALOFALK enemas contain the following excipients: carbomer 934P, disodium edetate, potassium acetate, potassium metabisulfite, purified water, sodium benzoate and xanthan gum.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30˚C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

SALOFALK enemas are supplied in opaque, concertina shaped LDPE squeeze bottles with a PVC applicator nozzle in cardboard cartons. The disposable unit consists of a PVC applicator tip protected by a LDPE cover and lubricated with white soft paraffin and/or liquid paraffin. The unit has a one-way valve to prevent back flow of the dispensed product.

SALOFALK enemas, 2 g/60 mL: Each carton contains 7 enemas in individual blister packs.
SALOFALK enemas, 4 g/60 mL: Each carton contains 1 or 7 enemas in individual blister packs.

Not all pack sizes are currently available in Australia.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

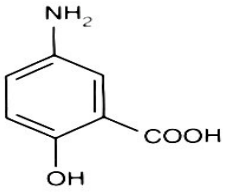
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Mesalazine is a white to greyish, voluminous powder, slightly pink in colour. It is practically insoluble in ethanol (90%), methanol (70%), water, ether, and chloroform, soluble in HCl (warmed 10% solution); soluble in NaOH (10% solution, with salt formation).

Proper name: 5-Aminosalicylic Acid, chemical name: 2-hydroxy-5-aminobenzoic acid, also referred to as 5-amino salicylic acid or 5-ASA. $C_7H_7NO_3$ = 153.1

Chemical structure



CAS number
89-57-6

7. MEDICINE SCHEDULE (POISONS STANDARD)

S4

8. SPONSOR

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9. DATE OF FIRST APPROVAL

15 May 2002

10. DATE OF REVISION

01 May 2025

SALOFALK® is a registered trademark of Dr. Falk Pharma GmbH, Germany.

Summary table of changes

Section changed	Summary of new information
4.4, 4.8	Addition of idiopathic intracranial hypertension
4.4, 4.9	Minor editorial changes for readability