Mesalazine (various brands) AMBER 0

Treatment of ulcerative colitis and Crohn's ileo-colitis in adults
– see www.lancashireandsouthcumbriaformulary.nhs.uk for further details

Background

Mesalazine is the active moiety of sulfasalazine and is recommended for the treatment of mild to moderate ulcerative colitis, as well as for maintaining remission in this condition. Certain brands of mesalazine are also licensed for maintaining remission in Crohn's ileo-colitis.

Dosage and Administration

Oral formulations

Name	Maintenance dose for Ulcerative Colitis	Treatment dose for active ulcerative colitis	Use in Crohn's ileo-colitis
Pentasa® (tablets/granules)	2g daily	Up to 4g ONCE daily or in 2-4 divided doses	-
Octasa® Preferred brand in Lancashire and South Cumbria	1.2-2.4g ONCE daily (or in divided doses)	2.4-4.8g ONCE daily (or in divided doses)	**Maintenance of remission:** 1.2-2.4g ONCE daily, alternatively daily in divided doses
Salofalk® (tablets/granules)	500mg THREE times daily	1.5-3g ONCE daily, preferably in the morning (or 0.5-1g THREE times daily)	-
Asacol® MR tablets (400mg MR tablets discontinued April 2024)	1.2-2.4g daily in divided doses	2.4-4.8g daily in divided doses	**Maintenance of remission:** Up to 2.4g daily in divided doses
Mezavant® XL	2.4g ONCE daily	2.4-4.8g ONCE daily, review treatment at 8 weeks	-

Rectal Formulations

Name	Maintenance dose for UC	Treatment dose for active UC	Use in Crohn's ileo-colitis
Pentasa® Suppository	Maintenance, ulcerative proctitis: 1g daily	Acute attack, ulcerative proctitis: 1g daily for up to 2-4 weeks.	unlicensed
Pentasa® liquid enema (retention)	1g at night	1g at night	unlicensed
Octasa® Suppository	1g at night	1g at night	unlicensed
Salofalk® Enema	2g at night	2g at night	unlicensed
Salofalk® Rectal Foam	unlicensed	Affecting the sigmoid colon and rectum: 2g at night (or in 2 divided doses)	unlicensed
Salofalk® Suppositories	unlicensed	Affecting the rectum: 0.5-1g, 2-3 times a day, adjusted according to the response. Alternatively, 1g at bedtime.	unlicensed
Asacol® Suppository	0.75-1.5g daily in divided doses. Last dose to be administered at bedtime	0.75-1.5g daily in divided doses. Last dose to be administered at bedtime	unlicensed
Asacol® Foam Enema	unlicensed	1-2g daily for 4-6 weeks (dose dependent on region affected; 1g rectosigmoid region **OR** 2g descending colon)	unlicensed

Monitoring

Pre-treatment	Baseline	FBC, U&E, eGFR, LFT
Monitoring	At 3 months*	FBC, U&E, eGFR, LFT
	Annually	U&E and eGFR (**consider** FBC and LFTs annually also – depending on risk factors)
Following dose change	Repeat FBC, LFT, and U&E 1 month after a dose increase, then as above.	

*Some manufacturers recommend more frequent monitoring, such as 14 days after starting, then every 4 weeks for 2 to 3 months, then 3 monthly thereafter.

Abnormal results:

STOP if renal function deteriorates

If AST or ALT are **greater than twice the upper limit of the reference range**, **STOP** and discuss with specialist.

*****Perform full blood count and stop treatment immediately if a blood dyscrasia or toxicity is suspected*****

Contraindications and Cautions for Use

Contraindications:

- Hypersensitivity to salicylates
- Gastric or duodenal ulcer
- Hypersensitivity to the active substance or any of its excipients
- Severe renal impairment (GFR <30ml/min)
- Severe liver impairment
- Blood clotting abnormalities

Special Warnings and Precautions:

- Avoid in patients with severe renal failure. Discontinue treatment if renal function deteriorates. Discuss with the renal team if appropriate.
- Hepatic impairment
- Use with caution in the elderly (>70 years)
- Patients with pulmonary disease, particularly asthma, should be closely monitored during treatment.
- Maintain adequate fluid intake.
- A careful assessment of the risk versus benefit should be carried out before use during pregnancy and breastfeeding. Consult specialists for further advice.

*****BLOOD DISORDERS: Patients and their carers should be advised to report any unexplained bleeding, bruising, purpura, sore throat, fever, or malaise that occurs during treatment*****

Side Effects

Common or very common
Arthralgia; cough; diarrhoea; dizziness; fever; gastrointestinal discomfort; headache; leucopenia; nausea; proteinuria; skin reactions; vomiting

Uncommon
Alopecia; depression; dyspnoea; myalgia; pancreatitis; paraesthesia; photosensitivity reaction; thrombocytopenia; flatulence.

Rare or very rare
Agranulocytosis; blood disorder; bone marrow disorders; cardiac inflammation; hepatitis; nephrotic syndrome; neutropenia; peripheral neuropathy; renal impairment; respiratory disorders; nephritis; pulmonary fibrosis.

Discontinue immediately if symptoms of acute intolerance syndrome occur such as abdominal pain, fever, severe headache and rash.

Always consult the latest version of the SPC at www.medicines.org.uk/emc/ for full details.

Drug Interactions

Concurrent use of other known nephrotoxic agents, such as NSAIDs, may increase the risk of renal toxicity.

Concomitant treatment in patients receiving azathioprine or 6-mercaptopurine can increase the risk of blood dyscrasias.

Lactulose or similar preparations, which lower stool pH, may prevent the release of mesalazine.when taken with some formulations.

This is not an exhaustive list of doses, side effects, cautions, contraindications or interactions.
For more information, please refer to the BNF via http://bnf.nice.org.uk/ or Summary of Product Characteristics.

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Bibliography

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