Sulfasalazine

Shared Care Guideline

Specialist details	Patient identifier
Name: _____	
Location: _____	
Tel: _____	**Date:** _____

Introduction

Licensed indications include: rheumatoid arthritis, induction and maintenance of remission of ulcerative colitis, treatment of Crohn's disease.

Unlicensed indications include: sero-negative spondylo-arthropathy, arthropathy related to inflammatory bowel disease, psoriatic arthritis.

Adult dosage and administration

Indications	Dosing schedule
Rheumatology (e.g. rheumatoid arthritis, sero-negative spondylo-arthropathy)	Initially 500mg daily, increased by 500mg at intervals of 1 week to a max of 2 - 3g daily in divided doses, according to tolerance and response. Occasionally doses above 3g/day are prescribed
Gastroenterology (e.g. Crohn's disease, ulcerative colitis)	1 - 2g orally four times a day until remission occurs, reducing to a maintenance dose of 500mg four times a day
	By rectum, in suppositories, alone or in conjunction with oral treatment 500mg - 1g morning and night after a bowel movement

Available as:

- 500mg tablets
- 500mg enteric coated tablets
- 250mg/5ml suspension
- 500mg suppositories.

Hospital specialist responsibilities

- Assess if the patient is suitable for treatment with sulfasalazine.
- Agree shared care with patient's GP.
- Advise GP on dose of sulfasalazine to be prescribed.
- Undertake baseline tests as indicated in monitoring table.
- Provide the patient/carer with relevant (preferably written) information on use, side effects and need for monitoring of medication.
- Review results of safety monitoring and request additional tests as required.
- Monitor disease response to treatment and need to continue therapy.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Provide any other advice or information for the GP if required.

<table>
<tr><th colspan="2">Monitoring table</th><th>Hospital specialist</th><th colspan="3">GP</th><th>Hospital specialist</th></tr>
<tr><th rowspan="2">Test</th><th rowspan="2">Indication</th><th rowspan="2">Pre-treatment baseline</th><th colspan="3">During treatment</th><th rowspan="2">At review</th></tr>
<tr><th>Until dose stable for 6 weeks</th><th>Next 3 months</th><th>Thereafter</th></tr>
<tr><td>FBC</td><td rowspan="3">Baseline assessment, dose adjustment</td><td rowspan="3">✓</td><td rowspan="2">Every 2 weeks</td><td rowspan="2">Every month</td><td rowspan="2">Every 3 months*</td><td rowspan="3">As part of review or as clinically indicated</td></tr>
<tr><td>LFTs</td></tr>
<tr><td>U&Es, eGFR</td></tr>
<tr><td>ESR/CRP
(Rheumatology and Gastroenterology only)</td><td>Disease activity scoring</td><td colspan="3">Every 3 months</td></tr>
<tr><td>Height & weight</td><td>Baseline assessment</td><td>✓</td><td colspan="3" rowspan="4">Not routinely required</td><td rowspan="4">If clinically indicated</td></tr>
<tr><td>Blood pressure</td><td rowspan="3">Baseline assessment, respiratory and TB screening</td><td rowspan="3">If clinically indicated</td></tr>
<tr><td>Chest x-ray</td></tr>
<tr><td>PFTs, TB screening if indicated</td></tr>
<tr><td colspan="2">Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding</td><td>✓</td><td colspan="3">At every consultation</td><td>✓</td></tr>
<tr><td colspan="7">If a further DMARD/JAK is added as combination therapy, or the dose is increased, the initial starting schedule should be reinstated. There may be clinical circumstances where the frequency of monitoring may vary and this should be specified by the initiating specialist.
* If stable for 12 months, no further routine monitoring is needed.</td></tr>
</table>

GP responsibilities

- Prescribe sulfasalazine.
- Arrange and record ongoing monitoring as advised by specialist (see monitoring table), ensuring practice systems are in place to recall patients for monitoring blood tests.
- Follow-up any non-compliance with the monitoring schedule. The risks of cessation of therapy versus risks of toxicity should be considered. Contact the specialist if treatment is stopped or further advice required.
- Report any adverse drug reactions to the initiating specialist and the usual bodies (eg. MHRA/CHM).
- Ensure no drug interactions with other medicines.
- Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding at every consultation.

Withhold sulfasalazine and contact specialist if:

- WCC < 3.5 x 10^9/L
- Neutrophils < 1.6 x 10^9/L
- **Unexplained** eosinophilia > 0.5 x 10^9/L
- Platelets < 120 x 10^9/L
- MCV > 105fL, (check B12 & folate & TFT)
- AST/ALT > 3 times the upper limit of normal (for results between 2 - 3 x ULN, continue sulfasalazine, repeat bloods and seek specialist advice) Minor elevations of AST/ALT are common
- If renal impairment develops (not always appropriate to stop but may need dose adjustment)
- Unexplained fall in serum albumin
- Oral ulceration / sore throat
- Unexplained rash / abnormal bruising
- New or increasing dyspnoea or dry cough.

Normal reference range may vary slightly between labs.
Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.

Adverse effects, precautions and contraindications

Common adverse reactions include insomnia, dizziness, headache, taste disorders, conjunctival and scleral infections, cough, pruritus, arthralgia, fever.
If patient becomes unwell in the first few weeks of treatment with **rash** (and sometimes fever) withhold sulfasalazine and discuss with specialist.
Crystalluria. Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment.
Rash / stomatitis: withhold and discuss with specialist if severe or persistent.
Blood disorders: leucopenia, thrombocytopenia. GPs should be alert to any unexplained bruising or bleeding.
Nausea/loss of appetite, abdominal pain, diarrhoea, vomiting: continue if possible. Slow increase in dose (new patients) and/or anti-emetic medication may resolve symptoms. If persistent, reduce maintenance dose.
Vertigo / tinnitus: symptoms may resolve on reduction of the dose.
Yellow discolouration: may colour urine, soft contact lenses or skin orange/yellow.
Pregnancy / contraception: sulfasalazine with folic acid supplementation (5mg/day) is compatible throughout pregnancy. Paternal fertility may be temporarily affected by sulfasalazine. Discuss with initiating specialist.
Breastfeeding. Women being treated with sulfasalazine should seek specialist advice.
G6PD: patients with glucose-6-phosphate dehydrogenase deficiency should be closely observed for signs of haemolytic anaemia.
Contraindications include:

- Hypersensitivity to sulfasalazine, sulphonamides, or salicylates
- Porphyria.

Common drug interactions

Digoxin: absorption of digoxin may be reduced. Review dosage requirement after sulfasalazine introduction.
Folic acid: absorption of folic acid may be reduced.
Mercaptopurine or azathioprine: possible increased risk of leucopenia.

Communication

For any queries relating to this patient's treatment with sulfasalazine, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC at www.medicines.org.uk or the BNF

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