SULFASALAZINE FOR USE IN ADULT GASTROENTEROLOGY
Shared Care Protocol

This protocol provides prescribing and monitoring guidance for sulfasalazine therapy. It should be read in conjunction with the Summary of Product Characteristics (SPC) available on www.medicines.org.uk/emc, the BNF and the Shared Care Protocol Responsibilities.

BACKGROUND FOR USE

Sulfasalazine is a disease modifying antirheumatic drug (DMARD) and aminosalicylate . Indications, dose adjustments and monitoring requirements for sulfasalazine (licensed and unlicensed indications) defined in this protocol are in line with national guidance published by the British Society for Rheumatology[1,] The British Society of Gastroenterology[2],NICE[5,6] and the European Crohn's and Colitis Organisation [7].

Sulfasalazine is an established drug with a known side effect profile. Its use in this protocol is limited to:

Gastroenterology

- Induction and maintenance of remission of ulcerative colitis.
- Evidence in Crohn's disease is limited[6].
- In many patients, its use has been superseded by newer aminosalicylate preparations (mesalazine, balsalazide, olsalazine) which have similar efficacy, are often better tolerated and lack the "sulpha" related side effects. It remains useful in some patients with inflammatory bowel disease with related seronegative arthropathy.

Rheumatology – see separate protocol

For all renal patients, supply of this medication will be provided in secondary care.

CONTRAINDICATIONS AND PRECAUTIONS

Contraindication	Action
G6PD deficiency or porphyria	Do not use - may cause haemolysis
Severe renal failure (GFR <10 ml/min)	Do not use
Men planning a family in the near future	Do not use. May cause reversible oligospermia (2 to 3 months)[2]
Sulphonamide or salicylate hypersensitivity	Do not use

Precaution	Action
Pregnancy and breastfeeding	If there is a high risk of disease flare, sulfasalazine can be continued in a dose not exceeding 2g per day. Folic acid should be prescribed in those trying to conceive and during pregnancy. Small amounts of drug can be excreted in the breast milk although this is not thought to be a risk to a healthy infant[1,4].
Renal impairment	May cause significant crystalluria. If mild or moderate renal impairment: increase fluid intake. Stop if GFR <10 ml/min.
Chickenpox or active skin lesions in shingles	Withhold sulfasalazine and inform specialist. For those with exposure to chickenpox or shingles and no history of infection/vaccination, passive immunisation with VZIG should be carried out.

DOSAGE [3,4]

Indication	Dose
Inflammatory bowel disease[2]	Acute attacks: 1g to 2g qds. Adjust dose to response until remission occurs. Ideally, night time interval between doses should not exceed 8 hours. May be given in conjunction with steroids as part of an intensive monitoring regimen for acute attacks. Maintenance dose: Doses may be reduced gradually to 500 mg qds, although many patients remain in remission using once to twice daily dosage.

- Tablets should be taken with or after food and swallowed whole with a full glass of water.
- Sulfasalazine 250mg/5ml oral suspension available.
- Maintain adequate fluid intake to avoid crystalluria.
- Patients should be supplied with a patient drug information leaflet from the manufacturers (available on EMC)

TIME TO RESPONSE

- Inflammatory bowel disease: A few days.

PRE-TREATMENT ASSESSMENT BY THE SPECIALIST

FBC, U&Es, LFTs and CRP

ONGOING MONITORING SCHEDULE

Gastroenterology	FBC, LFT, U&Es and CRP monthly for the first 3 months and every 3 months thereafter. If, following the first year, dose and blood tests are stable, monitor every 6 months. Following dose increase, check FBC and LFTs after one month.

In addition to absolute values for haematological indices, a rapid fall or consistent downward trend in any value should prompt caution and extra vigilance. In order to monitor trends, it is recommended that all blood test results are entered in the patient held monitoring booklet.

Side Effects	Action
WBC <3.5 x 10^9/l Neutrophils <2.0 x 10^9/l Platelets <150 x 10^9/l	Withhold and discuss with specialist.
Liver function >2.0 fold rise in AST/ALT	Withhold and look for alternative causes. Repeat LFTs. If abnormal, discuss with specialist.
MCV >105 fl	Check folate, TFT, B_{12} and treat if appropriate. If WBC normal, repeat in 4 weeks.
Acute widespread skin rash	Withhold and seek urgent specialist advice. If it presents with unexplained fever, FBC required.
Oral ulceration	Withhold, investigate alternative cause. If it settles promptly, re-challenge with a lower dose. If symptoms recur stop and contact specialist. If this presents with unexplained fever, FBC required.
Abnormal bruising or severe sore throat	Withhold and check FBC.
Nausea, vomiting, dizziness headache	Often transient. If possible, continue with use of anti-emetic or reduce dose by 500 mg.
Diarrhoea	Reduce dose by 500 mg. If persistent, consult rheumatologist.
Soft contact lenses	Can cause staining.
Discolouration of urine	Reassure patient that yellow/brown discolouration is ok.

- Sulfasalazine can be withheld for a few days without inducing a flare.
- Annual flu vaccine is recommended.
- NSAIDs may be continued.

DRUG INTERACTIONS [4,3]

Digoxin: Sulfasalazine may reduce digoxin absorption.
Folic acid: Sulfasalazine may impair folate absorption.
Azathioprine: Sulfasalazine may produce additive toxic effects on bone marrow.
Methotrexate: Sulfasalazine may increase the risk of nausea.
Mercaptopurine: Sulfasalazine may increase risk of leucopenia.

CONTACT DETAILS

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