SHARED CARE GUIDELINE

Homerton University Hospital NHS
NHS Foundation Trust

City and Hackney NHS
Teaching Primary Care Trust

SULFASALAZINE

INTRODUCTION

Sulfasalazine tablets are licensed for the:
a) Induction and maintenance of remission of ulcerative colitis; treatment of active Crohn's Disease.
b) Treatment of rheumatoid arthritis, psoriatic arthritis and reactive arthritis, which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs).
Sulfasalazine is a combination of 5-aminosalicylic acid (5-ASA) and sulfapyridine; sulfapyridine acts as a carrier to the colonic site of action where bacteria cleave the drug.

DOSE AND ADMINISTRATION

Ulcerative colitis and Crohn's disease
Adults including the elderly
Maintenance Therapy: With induction of remission reduce the dose gradually to **4 tablets** per day (500mg per tablet). This dosage should be continued indefinitely, since discontinuance even several years after an acute attack is associated with a four fold increase in risk of relapse. In the case of acute attacks which are normally managed by the specialist their advice should be sought before using the dose regimes shown below which, although licensed are rarely used.
Severe Attack: Sulfasalazine **2-4 tablets** four times a day may be given in conjunction with steroids as part of an intensive management regime. Rapid passage of the tablets may reduce effect of the drug.
Night time interval between doses should not exceed 8 hours.
Moderate Attack: **2-4 tablets** four times a day may be given in conjunction with steroids.
Mild Attack: **2 tablets** four times a day with or without steroids. Sulfasalazine may be administered by the rectal route as enemas containing 3g in 100ml. One enema may be given daily preferably at bedtime. Suppositories containing 500mg sulfasalazine may be used at a dose of 1 or 2 suppositories morning and evening.

Children; for completeness the doses recommended are:
The dose is reduced in proportion to body weight.
Acute Attack or relapse: **40-60mg/kg** per day
Maintenance Dosage: **20-30mg/kg** per day
Sulfasalazine Suspension (250mg/5ml) may provide a more flexible dosage form

Rheumatoid arthritis, psoriatic arthritis and reactive arthritis - Starting dose is **500mg** daily as ***enteric-coated*** tablets increased by 500mg at intervals of one week to a maximum of **2-3g** daily in divided doses.

Sulfasalazine tablets should be swallowed whole and not chewed; indigestion remedies should not be taken at the same time of day as sulfasalazine.

CAUTIONS

- Known or suspected G-6PD deficiency
- Slow acetylator phenotype
- Moderate renal or severe liver impairment

CONTRA-INDICATIONS

- Hypersensitivity to sulphur compounds or salicylates
- Children under 2 years

SIDE- EFFECTS

- Hypersensitivity reactions (fever, pruritis, photosensitisation, exfoliative dermatitis, anaphylaxis)
- Blood disorders (leucopenia, neutropenia, thrombocytopenia, stomatitis, megaloblastic anaemia)
- Gastrointestinal disturbances (nausea, vomiting, diarrhoea, abdominal pain)
- CNS disturbances (insomnia, vertigo, tinnitus, depression, hallucinations)
- Kidney reactions (proteinuria, crystalluria, haematuria)
- ***May colour the urine orange and stain certain soft contact lenses***
- Reversible male subfertility

See BNF and Summary of Product Characteristics for comprehensive list.

MONITORING STANDARDS FOR SULFASALAZINE

The following standards have been agreed for the monitoring of sulfasalazine.

Pre-treatment FBC, LFTs, U&Es, Creatinine

Monitoring FBC, LFTs monthly for first 3 months, and then every 3 months thereafter. If stable for the year, tests at 6 monthly intervals will suffice.

U&Es, Creatinine every 6 months

(More frequent monitoring may be required in rheumatoid arthritis, specialist to specify)

EVENTS AND ACTION

	Laboratory Events	Values	Action
•	Elevation in liver enzymes (AST, ALT) **NOT** ALK PHOS	>2x Normal	**Stop,** repeat LFTs, (concurrent NSAIDs in rheumatoid arthritis may cause this). Discuss with specialist.
•	MCV	> 110 fl	No action if RBC folate, serum B12, TFT and LFTs are normal. Consider haematological opinion.
•	WBC	< 3.0 x 10^9/L	**Stop**, repeat FBC in 1 or 2 weeks. Discuss with specialist.
•	Neutrophils	< 1.5 x 10^9/L	
•	Platelets	< 100 - 150 x 10^9/L	
•	Sequential falls in WBC or neutrophils	> 10% on 3 occasions	**Stop +** seek advice
•	Sequential falls in Platelets	> 10% on 3 occasions	**Stop** – unless falls are from high level e.g. 600, 500, 400 x 10^9/L, which are a response to treatment.

Symptoms	Management
• Dyspepsia, nausea	Reduce dose. Take with food; try anti emetic **Stop** if persistent or unacceptable. Enteric coated tablets may be tried if patient is taking plain tablets.
• Rash	Often non-specific erythematous, dry and itchy. **Stop drug** and refer for advice if severe. Consider using 1% hydrocortisone and /or antihistamines. Consider other causes of rash.
• Oral ulceration, stomatitis	**Stop if severe** and discuss with rheumatologist. Consider carbenoxolone or benzydamine mouthwashes.
• Fever / Flu like illness	**Stop drug**. Unusual hypersensitivity reaction.
• Discoloration of urine and/ or soft contact lenses	Reassure patient

REMEMBER if unsure at any point: Contact the various Specialists and or Specialist Nurse/Nurse Practitioner via the Homerton Hospital switchboard on 020 8510 5555.