Sufasalazine in Ulcerative Colitis, Crohn's disease and Rheumatoid arthritis

Licensed indications and key points

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.
Vaccinations: live vaccines should be AVOIDED (i.e. oral polio, MMR, BCG and yellow fever and oral typhoid). Passive immunization should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients exposed to active chickenpox or shingles.
Annual flu and pneumococcal vaccination is recommended.
Pregnancy and breastfeeding. If sulfasalazine is used in pregnancy, the dose should not exceed 2g/day and folate supplements should be given.
Sulfasalazine can be prescribed to men of childbearing potential although there may be transient reversible oligospermia.
Taking sulfasalazine whilst breast feeding is thought to be safe for healthy infants.

Initiation and maintenance

Sulfasalazine is available as orally administered 500mg enteric coated tablets, 50mg/ml suspension and as a 500mg rectally administered suppositories.
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 **2g to 3g** daily in divided doses.

Ulcerative colitis and Crohn's disease in adults		
	Mild to moderate and severe acute attack	Maintenance therapy:
Oral	1g to2g FOUR times daily in conjunction with steroids until remission	500mg QDS daily
Rectal	0.5g to 1g TWICE daily alone or in conjunction with oral therapy	
Ulcerative colitis and Crohn's disease in children		
Oral	Acute Attack or relapse	40mg/kg to 60mg/kg per day
	Maintenance Dosage	20mg/kg to 30mg/kg per day

Sulfasalazine tablets should be swallowed whole and not chewed; indigestion remedies should not be taken at the same time of day as sulfasalazine.
Sulfasalazine Suspension (250mg/5ml) may provide a more flexible dosage form.

Monitoring

MONITORING	RESPONSIBILITY	CONDITIONS	TESTS
Pre-treatment	Hospital team	All	FBC, ESR, U&Es and LFTs. **Results to be known before drug is commenced**
Initiation to stabilisation	Hospital team/GP	All	FBC, ESR, U&Es, LFTs monthly for **three months**.
Ongoing	GP	All	• FBC, LFT, U&Es **3 monthly** If dose and monitoring is **stable after one year**, then no routine monitoring needed (annual blood tests recommended) Ask about rash and oral ulceration at each visit.

Criteria for managing events & symptoms occurring during Sulfasalazine therapy in primary care

LABORATORY EVENTS	VALUES	ACTION
MCV	Increased > 105 fL	**Seek specialist advice**. Check TFT, B12 and folate, Monitor LFTs as could be dose-related.
WBC	< 3.5 x 10^9/L	**Seek specialist advice**, repeat FBC in 1 or 2 weeks.
Neutrophils	< 1.6 x 10^9/l – consider stopping drug 1.6-2 x 10^9/l – check trend	
Platelets	< 140x 10^9/l - consider stopping drug	
Haemoglobin	<80g/dL - consider stopping drug 80-100g/dL – check trend	
Significant deterioration in renal function	Creatinine increase >30% over 12 months or calculated GFR <60ml/min	**Seek specialist advice.** Caution dose reduction advised in renal impairment
Elevation in liver enzymes (AST, ALT) or falling albumin	>2x upper limit of normal (ULN) - consider dose adjustment; >3x ULN - consider stopping drug Albumin <30 g/l - please review patient for other medical problems	**Seek specialist advice.**

SYMPTOMS	MANAGEMENT
Abnormal bruising/ bleeding or severe sore throat	**Check FBC** immediately and withhold sulfasalazine until results available. Follow relevant course of action from table above Discuss with specialist team if necessary.
Dyspepsia, nausea, dizziness, headache	**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
Unexplained acute widespread rash	Often non-specific erythematous, dry and itchy. **Stop drug** and Seek for advice (dermatology) 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

Drug interactions, contraindications and precautions

See BNF and manufacturer's SPC Home - electronic Medicines Compendium (eMC) for up-to-date advice

Prescribing responsibilities

Refer to principles of shared care document

Contact details

Consultant, medical staff and nurse practitioners at the Basildon and Thurrock University Hospitals NHS Foundation Trust (BTUH) are available to give advice and can be contacted either through the main hospital switchboard or direct.

Department / Specialist	Contact Telephone Number
Hospital switchboard – ask for specialist or On-Call specialist rheumatologist or gastroenterologist out-of-hours	01268 524900
Rheumatology	01268 598461
Email contact for shared care queries ONLY: RheumatologyOsteoporosisPOD@btuh.nhs.uk) (48 hours response)	
Gastroenterology	01268 524900 ext 3970 or 3987

Local Enhanced Services for Shared Care Monitoring

Level 1: The prescribing of this medication only.
Level 2: The prescribing and monitoring of this medication and disease

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Shared Care Guidelines are also available electronically via: https://basildonandbrentwoodccg.nhs.uk/your-health/medicines-management	
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