South West Yorkshire
Area Prescribing Committee

SULFASALAZINE EC - Shared Care Guideline

Introduction

General Statements	• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and primary care prescriber. • The primary care prescriber must reply in writing to the request for shared care as soon as practicable if unwilling to participate. • Responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and primary care notes. • The agreement to consider the use of a shared care guideline should only be considered when the patient's clinical condition is stable or predictable.
Indication	Rheumatoid arthritis (licensed), other inflammatory arthritides (unlicensed)

Individual's Responsibilities

Hospital Specialist's Responsibilities	➢ Record patient consent to unlicensed use in medical notes (if applicable) ➢ Baseline monitoring and initial prescribing until the patient is established on treatment (minimum of 8 weeks). ➢ Monitoring disease progression and response to treatment ➢ Supporting and advising primary care prescribers ➢ Monitoring booklets are available and may be beneficial in certain circumstances, for example if the patient receives blood monitoring at a location where results are inaccessible to the clinician. In these situations the Hospital Specialist will communicate this fact to the primary care prescriber at the point when prescribing and monitoring is transferred Ensure that the patient has an adequate supply of medication until primary care prescriber supply can be arranged. ➢ Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the primary care prescriber. ➢ Provide patient with rheumatology nurse helpline contact number.
Primary Care Prescribers Responsibilities	➢ Ensure hospital is notified if unwilling to undertake prescribing and monitoring when requested ➢ Prescribing following written request from specialist care ➢ Ensure monitoring is undertaken according to shared care guideline and only continue prescription if compliance with monitoring and results satisfactory ➢ Follow guidance in the event of reaction or abnormality, record it and report back to the specialist ➢ Update patient's monitoring booklet as appropriate (including test dates & results, when available) ➢ Ensure no drug interactions with concomitant medicines ➢ To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring ➢ Encourage influenza vaccination as per Green Book

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Monitoring Required	**Baseline** – FBC, U&E including urinalysis, creatinine, LFTs, serum folate The Hospital Specialist must confirm to the primary care prescriber which stages of the maintenance monitoring have already been completed at the point when prescribing and monitoring are transferred to the primary care prescriber **Maintenance -** FBC, LFT 2 weekly for 8 weeks, monthly for 4 months, then 3 monthly U&E and urinalysis; monthly for the first 3 months, then only if clinically indicated If following the first year, dose and blood results have been stable, monitoring of blood for toxicity may be discontinued
When and How to Discontinue Treatment	Loss of efficacy, intolerance, abnormal bloods (see table) Refer back to specialist care
Information given to the patient	Patient information leaflet for sulfasalazine and monitoring booklet (provided by hospital specialist). Patients should be advised to report any unexplained bleeding, bruising, purpura, sore throat or fever.
Contact Details	Documented in letter from specialist care to primary care prescriber

Product Information

The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics

Dosage	RA and inflammatory arthritides – enteric coated tablets, initially 500mg daily increased by 500mg at intervals of one week to a **maximum of 2-3g/day in divided doses.**
Adverse Effects	Marrow aplasia – the CHM has recommended that patients should be advised to report any unexplained bleeding, bruising, purpura, sore throat, malaise, pallor or fever. A blood count should be performed and the drug stopped immediately if there is suspicion of a blood dyscrasia **Mucocutaneous**–rash including rare incidences of Stevens Johnson syndrome or exfoliate dermatitis **GI** – nausea, vomiting, allergic hepatitis, loss of appetite, taste disturbances Reversible oligospermia and infertility Orange staining of extended wear soft contact lenses and urine Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Precautions and Contra-indications	Contraindications ➢ Sulphonamide and salicylate hypersensitivity ➢ Patients with porphyrias Precautions ➢ Renal and hepatic impairment ➢ ANA positive (risk of drug-induced SLE) ➢ Pregnancy (can be used up to 2g/day with folic acid 5mg daily ➢ Breastfeeding (small amount found in breast milk; theoretical risk of neonatal haemolysis especially in G6PD-deficient infants) ➢ G6PD deficiency (risk of haemolysis) ➢ Severe allergy or bronchial asthma
Clinically relevant Drug Interactions and	Reduces absorption of **digoxin** Risk of marrow toxicity with **azathioprine** or **mercaptopurine** Refer to the current BNF and www.medicines.org.uk/emc/ for complete and

their management	up to date information.

Recommended action for abnormal results

Investigation	Action
WBC <3.5 x10^9/L Neutrophils < 2 x10^9/L Platelets < 150 x10^9/L	Stop and contact Specialist Care
Hb fall >1g in 4 weeks or below 10g	Check for increased disease activity Ask about NSAID use and symptoms of GI blood loss or dyspepsia and stop NSAIDS if implicated. Check MCV and iron studies Consider endoscopy
ALT above normal range but below 3x upper limit ALT > 3x upper limit	Repeat bloods every 2 weeks Ask patient about viral/bacterial infections Check that it is not due to another drug or NSAID particularly diclofenac and stop this first Stop and contact Specialist Care
MCV over 105fL	Check B12 and folate

Recommended action for adverse effects

Adverse event	Action
Abnormal bruising or severe sore throat	Check FBC immediately and withhold until result available
Itching	Reduce dose* and review
Rash	Check for other causes e.g. complications of disease, vasculitis, steroid effects. Mild – reduce dose* Severe – stop & contact Specialist Care
Oral ulcers, stomatitis	Check WBC Check for candida & treat accordingly Mild- advise mouthwash and increased dental hygiene Severe – stop & contact Specialist Care
Nausea, anorexia, vomiting,	Mild - reduce dose*, consider anti-emetic, Severe – stop & contact Specialist Care
Diarrhoea	Check for other cause Mild -treat symptomatically reduce dose* if persistent. Stop if severe & contact Specialist Care
Headache	Check for other causes Mild – try analgesia and reduce dose* Severe – stop & contact Specialist Care

*Specific dosage reduction advice is not always possible, and will vary according to the patient's individual circumstances. As most adverse effects are likely to occur during or shortly after dose titration, it is suggested that if adverse effects do occur, the dose is reduced to the previously tolerated dose and the patient assessed accordingly. If this is ineffective, consider discontinuation and seek advice from the hospital specialist