Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)

SHARED CARE

Drug: SULFASALAZINE **Protocol number CV 21**

Indication: RHEUMATOID ARTHRITIS

General guidance

This protocol sets out details for the shared care of patients taking **sulfasalazine** and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Sulfasalazine (Salazopyrin) is widely use for the long term treatment of rheumatoid arthritis. There are two preparations in use, Salazopyrin EN, (oval, film coated) and generic sulfasalazine (round, uncoated). The former is considered to have fewer GI side effects.

Responsibilities

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Initiate therapy following full discussion with the patient of benefits and risks.
3. Baseline and continued monitoring until patient is stabilised of biochemical parameters (see page 2)
4. A patient information leaflet will be provided. The patient will be informed to report immediately to their GP any unexplained bleeding, bruising, purpura, sore throat, fever or malaise.
5. Initiate sulfasalazine according to dosage regimen and undertake monitoring of clinical response and side effects.
6. When a GP positive response to Shared Care has been received and patient has been stabilized send a letter to GP "handing over" the Shared Care of the patient to the GP.
7. Respond to any request from GP to review the patient due to adverse effects of therapy.
8. Advise the GP on continuing or stopping sulfasalazine therapy following medical review of the patient and associated drug therapy.
9. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe **sulfasalazine** as part of the shared care agreement.
3. Monitor the general health of the patient
4. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
5. Recommend that patient receives pneumococcal vaccination and yearly influenza vaccination as well as Zostavax as part of the national shingles immunisation programme.
6. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with sulfasalazine.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst taking sulfasalazine.

Dosage Regimen

Typical dose: 500mg/day increasing by 500mg weekly increments to a maximum of 2-3g /day if tolerated. Occasionally doses above 3g/day may be prescribed by the rheumatologist.

Monitoring

Before treatment

FBC, Creatinine and Electrolytes, LFTs and Anti-nuclear antibodies (ANAs)

During Treatment

FBC & LFTs every 2 weeks for the first 3 months. Thereafter, routine monitoring of bloods is not required unless toxicity suspected.

Patient should be asked about the presence of rash or oral ulceration at each visit.

Urgent FBC if patient complains of intercurrent illness during initiation of treatment.

Following changes in dose

Repeat FBC and LFTs 2 weeks after dose increases

Withold sulfasalazine and discuss with specialist if any of the following occurs: -

WBC	$< 4.0 \times 10^9$/L
Neutrophils	$< 1.5 \times 10^9$/L
Platelets	$< 150 \times 10^9$/L
AST/ALT	> 2-fold rise (from upper limit of reference range)

Abnormal bruising or severe sore throat (check FBC immediately)

Unexplained acute widespread rash

Oral ulceration

If MCV >105fl – check serum folate and B12 and TSH.
Treat any underlying abnormality. If results normal discuss with specialist team.

Nausea/dizziness/headache – if possible continue, may have to reduce dose or stop of severe symptoms

Please note that in addition to absolute values for haematological indices a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance

Adverse effects

Mucocutaneous:	Skin rash and stomatitis - stop the drug. Desensitisation may be achieved if the drug is recommenced at a lower dose.
Haematological:	Macrocytosis - secondary to folate deficiency. Neutropenia - generally within the first two months of treatment (usually unassociated with thrombocytopenia) - reversible on stopping drug (see above).
Gastrointestinal:	Anorexia and nausea - common, mild nausea may be self limiting with time and should respond to a reduction in the dose and gradual increase. If severe may need to stop drug.
Hepatic:	Hepatitis, and pancreatitis may occur - stop drug (see above)
Renal:	In moderate renal impairment may cause significant crystalluria and must ensure high fluid intake. Avoid in severe renal failure.
Other:	May cause drug-induced lupus-like syndrome in slow acetylators of the drug (not necessary to assess acetylator phenotype).

Notable drug interactions (refer to BNF & SPC)

Azathioprine or Mercaptopurine – may contribute to bone marrow toxicity

Cardiac glycosides – sulfasalazine possibly reduces the absorption of digoxin

Special Recommendations

Sulfasalazine is contraindicated in patients with a hypersensitivity to sulphonamides/co-trimoxazole or aspirin.

Sulfasalazine may discolour contact lenses.

Sulfasalazine can be prescribed to men of childbearing potential but there may be a transient reversible oligospermia.

If sulfasalazine is prescribed during pregnancy, an analysis of risks and benefits to the mother should be undertaken, against the possible risk related to the unborn child and doses should not exceed 2g/day.

A folic acid supplement should be prescribed to those trying to conceive and during pregnancy.

Small amounts of the drug may be excreted in breast milk although these are not thought to be a risk to a healthy infant.

Contact Details

If you suspect an adverse reaction has occurred please stop the drug and contact the rheumatology department at the University Hospital of Wales.

The contact numbers for the rheumatology department are 02920 742627, 02920 742626 and 02920 743184. The fax number is 02920 745017. The rheumatology nurses help line number is 02920 748191.

Date of next review December 2021