**Drug Name: Sulfasalazine Enteric Coated (EC)**

**Clinical Indications:** For the treatment of Rheumatological inflammatory diseases

**Version:** 1.2  **Date Approved:** January 2013  **Review Date:** January 2015

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**Sulfasalazine Enteric Coated (EC) - for control of active joint inflammation**

**AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE**

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Sulfasalazine EC can be shared between the specialist and general practitioner or non-medical prescriber in primary care (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In that case, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe drugs for this treatment, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Rheumatological inflammatory diseases are under regular specialist follow-up. This provides an opportunity to discuss and to monitor drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

**RESPONSIBILITIES and ROLES**

<table>
<thead>
<tr>
<th>Specialist responsibilities</th>
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</thead>
<tbody>
<tr>
<td>• FBC, liver and renal function are within normal parameters to allow Sulfasalazine EC to commence.</td>
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<tr>
<td>• If abnormalities found at baseline inform GP as soon as possible.</td>
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<td>• Initiate treatment with Sulfasalazine EC or advise GP on initiating treatment.</td>
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<td>• Discuss the benefits and side effects of treatment with the patient and inform GP this has occurred.</td>
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<td>• Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.</td>
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<td>• Review the patient's condition and monitor response to treatment regularly where indicated.</td>
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<td>• Advise GP if monitoring is needed, and the frequency.</td>
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<td>• Monitor any other parameters considered necessary, or advise GP on which to monitor.</td>
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<td>• Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, any results of the monitoring undertaken, and assessment of adverse events.</td>
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<td>• Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.</td>
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<td>• Advise GPs on when to stop treatment (if appropriate).</td>
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<tr>
<td>• Report adverse events to the MHRA via Yellow Card Scheme.</td>
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<td>• Ensure that clear backup arrangements exist for GPs to obtain advice and support.</td>
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Any queries relating to this Shared Care Protocol contact the Clinical Effectiveness Pharmacist (01592) 226915

Document approved by NHS Fife Area Drugs & Therapeutics Committee on behalf of NHS Fife. Date: February 2013

Ishtiaq Mohammed, Clinical Effectiveness Pharmacist
General Practitioner responsibilities

- Reply to the request for shared care as soon as practicable.
- Prescribe Sulfasalazine EC at the dose recommended.
- Adjust the dose as advised by the specialist.
- Monitor any parameters considered necessary, if agreed with the specialist to do so.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the specialist and to the MHRA via the Yellow Card Scheme.

Patient’s role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3. Report any adverse effects to the specialist or GP, in particular sore throats, fever, jaundice and severe malaise.

BACK-UP ADVICE AND SUPPORT

<table>
<thead>
<tr>
<th>Contact details</th>
<th>Telephone No.</th>
<th>Email address:</th>
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</thead>
<tbody>
<tr>
<td>Specialist: Rheumatology Dept</td>
<td>01592 648193 01592 265967 (fax)</td>
<td><a href="mailto:janegibson@nhs.net">janegibson@nhs.net</a> <a href="mailto:helenharris@nhs.net">helenharris@nhs.net</a> <a href="mailto:johnmclaren@nhs.net">johnmclaren@nhs.net</a> <a href="mailto:sharoncullinane@nhs.net">sharoncullinane@nhs.net</a></td>
</tr>
<tr>
<td>Other: ADTC website - FRDU adverse drug reaction document</td>
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SUPPORTING INFORMATION (taken from the SPC)

Licensed indications
Indications – active joint inflammation, usually supported by indices of inflammation.

Dosage and Administration
500mg enteric coated tablets (Salazopyrin EN®) should be used – these are licensed and have a lower incidence of headache and nausea.
500mg daily, increased by 500mg weekly to usual maintenance dose of 1000mg twice or three times daily.
Maximum dose is 40mg/kg/day.

Contraindications and precautions for use
- Contra-indicated in patients hypersensitive to sulphonamides/co-trimoxazole or aspirin.
- Cautioned in glucose-6-phosphate dehydrogenase deficiency (may cause haemolysis), and in moderate renal impairment (may cause significant crystalluria).
Hypoglycaemia has occurred in patients receiving sulfonamides. Patients receiving sulfasalazine EC and hypoglycaemic agents should be closely monitored.

- Rarely oligospermia which is reversible within 2 – 3 months of discontinuation of drug.

- If sulfasalazine EC is to be prescribed during pregnancy the Rheumatologist should discuss this with the patient. Folic acid 5mg od 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.

**Side Effects (also state any specific side-effects which require the consultant to be notified)**

- Headache, Gi disturbance - especially nausea, hypersensitivity reactions (most commonly rash), pruritis, loss of appetite, discoloration of urine, raised temperature, dizziness and cough.
- Rare: acute pancreatitis, hepatitis, nephrotic syndrome, blood disorders (cytopenias).

For a complete list of side effects see BNF/ Summary of product Characteristics.

Treatment should be withheld and the Rheumatology Department contacted if:

- **NEUTROPHILS < 1.5 x 10^9**
- **PLATELETS < 100 x 10^9**
- >2 fold increase in ALT (from upper limit of reference range)
- **RASH or ORAL ULCERATION**
- **MCV > 105 fl** (check folate levels, as Sulfasalazine EC can impair folate absorption)
- **ABNORMAL BRUISING or SORE THROAT** (urgent F.B.C.)

Monitoring (State specific monitoring to be undertaken by the GP / Consultant) see FRDU blood monitoring forms (ADTC website)

**Rheumatologist responsibilities:**

FBC, liver and renal function are within normal parameters to allow Sulfasalazine EC to commence.

**General Practitioner responsibilities:**

- While taking Sulfasalazine EC patients will require 2 weekly FBC for 6 weeks.
- If monitoring remains normal, this can be reduced to monthly for 3 months, then 3 monthly for the first year.
- Liver function should be checked MONTHLY for the first 12 weeks. If monitoring remains normal, this can be reduced to 3 monthly.
- If monitoring is stable in the first year then FBC & Liver function can be reduced to 6 monthly for the second year. If FBC & Liver function remains normal after this, then monitoring can be discontinued.
- FBC & Liver function should be checked after one month after subsequent dose increases.

**Drug Interactions**

- Uptake of digoxin and folate may be reduced.
- Azathioprine may contribute to bone marrow toxicity.

**Cost** (September 2012)

- Salazopyrin EN 112 X 500mg tablets = £8.43
- Sulfasalazine EC 112 X 500mg tablets = £8.43

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