SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR ORAL SULFASALAZINE (ADULTS)

This SCA is applicable for ALL conditions/specialities.

If sulfasalazine is being used as combination therapy with methotrexate both SCAs must be referred to. The correct Monitoring Schedule for DMARDS, i.e. single agent or combination therapy should be followed.

Note: This document should be read in conjunction with the current Summary of Product Characteristics (SmPC).

Patient safety is paramount. The prescriber who prescribes the medicine legally assumes clinical responsibility for the drug and the consequences of its use.

GENERIC NAME (formulations and strength)

Name: Sulfasalazine (Tablets®, EN tablets and Oral Suspension)

Formulation: Tablet and suspension

Strength: 500mg Tablet, 250mg per 5mL Suspension

STATUS OF MEDICINE

Licence status: Licensed for the treatment of rheumatoid arthritis, ulcerative colitis and Crohn's disease. **Note:** Only the EN tablet formulation is licensed for rheumatoid arthritis and is generally better tolerated.

Formulary status: Formulary

Black triangle medicine: NO

Risk minimisation materials: NO

CONDITION(S) TO BE TREATED UNDER THIS SCA

Treatment and management of:

- Rheumatoid arthritis
- Ulcerative colitis
- Crohn's disease

TYPICAL DOSAGE REGIME	
Licensed dose	See Specialist service/SmPC for advice – variable according to condition being treated
Route of administration	Oral

TYPICAL DOSAGE REGIME	
Recommended starting dose	See Specialist service for advice – variable according to condition being treated
Titration dose/increment	See Specialist service for advice
Maximum dose	See Specialist service for advice
Situations requiring dose adjustment	See Specialist service for advice and Monitoring Schedule for DMARDs
Duration of treatment	See Specialist service for advice

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

- Baseline as per Monitoring Schedule for DMARDs:
  - Full Blood Count (FBC), Liver Function Tests (LFTs), and Urea and Electrolytes (U&Es)
- Copy of baseline results to be shared with primary care.
- Advise patient to contact their physician if considering pregnancy or immediately should pregnancy occur.
- Request for initiation of therapy and recommendations for dose increments to Primary Care.
- Monitoring clinical response to treatment and advising on final dose required for the patient. Clinical decision regarding final dose required for patient.

RESPONSIBILITY OF PRIMARY CARE/PRESCRIBING CLINICIAN

A Practice agreeing to prescribe sulfasalazine should:

- Prescribe medication under the guidance of the Consultant from the relevant specialist service.
- Checking before prescribing each instalment of medication that the monitoring is up to date and that results are within a satisfactory range.
- Note: for individuals referred for vaccinations by the specialist service it is ideal to wait for vaccinations before starting immunosuppressive treatments. However this risks not controlling the autoimmune condition quickly which can negatively affect long term prognosis. Therefore specialties do not insist on a delay in starting immunosuppressive treatment to allow for vaccinations and recommend vaccinations happen as soon as possible after starting immunosuppressive treatment.
- Ensure that the relevant monitoring requirements have been undertaken at the correct frequency.
- The General Practitioner (GP) has primary responsibility for monitoring according to the Monitoring Schedule for DMARDs and review results.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- Ensure the GP is aware that the drug can cause:
  - Leucopenia
  - Infection
  - Crystalluria

- Patients should be asked about the presence of sore throat, abnormal bruising or bleeding at each visit.
- Ensure when the patient has an intercurrent illness FBC, U+E and LFTs are done and abnormal results are acted upon promptly. If an intercurrent illness occurs, when completing laboratory request always include details of the patient's medication.
- If bloods are taken due to intercurrent illness, ensure they are monitored and action taken as per the Monitoring Schedule for DMARDs.
- Infection - During a serious infection sulfasalazine should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection.
  It can be considered appropriate to continue these drugs in patients with minor or uncomplicated viral infections or, if deemed clinically appropriate by the Specialist, in patients requiring long term antibiotic prophylaxis e.g. for prevention of recurrent UTIs.
- Contact the relevant specialist service in the event of a drug reaction, monitoring abnormality, or if you are concerned in any way regarding the current treatment regime.
- Be alert for any of the known adverse reactions.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- The patient should be encouraged to ensure blood tests are undertaken at the correct intervals.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- If something unexpected occurs contact Consultant for relevant specialist service.
- Notify consultant/specialist service if drug is stopped.

MONITORING

Refer to the NHSG Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals.

If sulfasalazine is being used as combination therapy with methotrexate both SCAs must be referred to. The correct Monitoring Schedule for DMARDS, i.e. single agent or combination therapy should be followed.

Primary Care are responsible to ensure results are reviewed and action taken as per monitoring guidance.

Note: In addition to absolute values for haematological or biochemical indices a rapid change or a consistent upward/downward trend in any value should prompt caution and extra vigilance.

RESPONSIBILITY OF THE PATIENT

- Take medication regularly as directed by the specialist/doctor.
- Attend hospital and GP clinic appointments as requested by specialist/GP practice. Failure to attend appointments may result in medication being reviewed/stopped.
- The patient should ensure all blood tests are undertaken at the correct intervals.
- Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen.

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (http://emc.medicines.org.uk/), the BNF/BNF for Children BNF (British National Formulary) | NICE

CONTRAINDICATIONS

For full detail please refer to the current Summary Product Characteristic (SmPC) available at www.medicines.org.uk

- Hypersensitivity to the active substance or to any of the excipients.
- Known hypersensitivity to sulfonamides or salicylates.
- Porphyria.
- Severe infections - during a serious infection sulfasalazine should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection.

PREGNANCY

Due to the folate depleting action of sulfasalazine primary care should prescribe 5mg daily of folic acid for all women planning a pregnancy on sulfasalazine, ideally starting 4 weeks before conceiving.

British Society for Rheumatology Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids from April 2023 states that sulfasalazine is safe in pregnancy and should be continued with adequate folate supplementation at 5mg daily throughout the entire pregnancy.

Women on sulfasalazine should be advised to notify their GP at least one month prior to planned conception as it is recommended all patients on sulfasalazine should receive 5mg folic acid in the periconception period and throughout the entire pregnancy.

BREAST-FEEDING

British Society for Rheumatology Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids from April 2023 states that sulfasalazine is safe in breastfeeding (in a healthy, full term infant). This is out with the product license which states patients should avoid breastfeeding while taking this medicine, but supported by specialist services.

COMMON SIDE EFFECTS

Blood and lymphatic system disorders	Leucopenia
Gastrointestinal disorders	Gastric distress, nausea, abdominal pain, diarrhea, vomiting and stomatitis
Skin and subcutaneous tissue disorders	Pruritus
Musculoskeletal and connective tissue disorders	Arthralgia

Psychiatric disorders	Insomnia
Nervous system disorders	Dizziness, headache and taste disorders
Respiratory, thoracic and mediastinal disorders	Cough
Other very common or common side effects	Conjunctival and scleral injection, tinnitus, proteinuria and fever. Yellow discolouration of skin and bodily fluids.

Some types of soft contact lenses may be stained by patients taking sulfasalazine, patients should be made aware.

Action abnormal monitoring results are per NHSG Disease Modifying Anti-Rheumatic Drugs (DMARDs) Monitoring Guidance.

The specialist service should be contacted if there are any patient specific issues or concerns regarding side effects or abnormal results.

COMMON DRUG INTERACTIONS (for a full list see SmPC)

For full detail of the numerous drug interactions with sulfasalazine please refer to the current Summary of Product Characteristics (SmPC) available at www.medicines.org.uk

- Some important interactions to consider include the following:
    - Digoxin - sulfasalazine administered concurrently with digoxin can result in reduced absorption and non-therapeutic serum levels
    - Sulfonamides - hypoglycemia has occurred in patients receiving sulfonamides. Patients receiving sulfasalazine and hypoglycemic agents should be closely monitored
    - Bone marrow suppression and leucopenia have been reported when the thiopurine 6-mercaptopurine or its prodrug, azathioprine, and oral salazopyrin were used concomitantly
    - Live vaccines should be avoided in patients taking sulfasalazine
    - Co-administration of oral sulfasalazine and methotrexate to rheumatoid arthritis patients did not alter the pharmacokinetic disposition of the drugs. However, an increased incidence of gastrointestinal adverse events, especially nausea, was reported.

This information is not intended to be a complete list of interactions. For further information consider appropriate reference sources such as SmPC/Vision system.

ADVERSE DRUG REPORTING

If an adverse reaction should occur, inform relevant medical practitioner as soon as possible.

Report to the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/

REFERENCES

- Salazopyrin Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of a concern being raised, the primary care practitioner should contact the referring consultant for the appropriate specialist service via the hospital switchboard, via their secretary, by email or letter, whichever is more appropriate. If the concern is urgent, and out of hours advice is required, the on call Registrar for the speciality may be contacted via the switchboard.

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