SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR SULFASALAZINE (ADULTS ONLY - NON-RENAL PATIENTS)

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 AND BRAND NAME (formulations and strength)

Name: Sulfasalazine (Salazopyrin 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

Treatment of rheumatoid arthritis; ulcerative colitis and Crohn's disease.

TYPICAL DOSAGE REGIME	
Licensed dose	See Specialist service/SmPC for advice – variable according to condition being treated
Route of administration	Oral
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:
  - Full Blood Count (FBC); liver function tests.
  - LFTs; urea, U&Es; lipids, urinalysis and blood pressure (BP).
- Copy of baseline results to be shared with primary care.
- Exclude pregnancy before starting therapy:
  - Give advice on contraception and tell patient to use contraception for at least 6 weeks after discontinuation of treatment.
  - Advise patient to contact their physician immediately should pregnancy occur.
- Initiation of therapy and recommendations for dose increments. This should remain under the control of the specialist service.
- Decision on final dose required for patient.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given; patients should be referred to receive these vaccines in accordance with local protocol.

RESPONSIBILITY OF PRIMARY CARE

A Practice agreeing to prescribe Sulfasalazine should:

- Prescribe medication under the guidance of the Consultant from the relevant specialist service.
- The General Practitioner (GP) has primary responsibility for monitoring according to the Monitoring Schedule for DMARDs
- 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 that the relevant monitoring requirements have been undertaken at the correct frequency.
- Ensure when the patient has an intercurrent illness FBC, U+E and LFTs are done and abnormal results are acted upon promptly.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- 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.
- The patient should be encouraged to ensure blood tests are undertaken at the correct intervals.
- It is responsibility of primary care to ensure that the medication is recorded on the patient's clinical medication record. This will facilitate central searches for annual vaccinations in order to ensure patients receiving DMARDs are called yearly by the HSCP teams for required vaccinations.

CARE WHICH IS THE RESPONSIBILITY OF THE PRESCRIBING CLINICIAN

- Prescribe medication under guidance of the relevant specialist service.
- Check before prescribing each instalment of medication that the monitoring is up to date and that results are within the normal range.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- If an intercurrent illness occurs, when writing laboratory request forms always include details of the patient's medication.
- If bloods are taken due to intercurrent illness, ensure they are monitored and contact hospital consultant to advise if results are out with range.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given, patients should be referred to receive these vaccines in accordance with local protocol.

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.

Note: If something unexpected occurs contact on call registrar or Consultant for the appropriate specialty. Notify the consultant if the drug is stopped.

MONITORING

Refer to the NHSG Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals. Results should be reviewed and action taken as per monitoring guidance.

RESPONSIBILITY OF OTHER HEALTHCARE PROFESSIONALS

N/A

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.
- Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen.
- The patient should ensure all blood tests are undertaken at the correct intervals.

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (http://emc.medicines.org.uk/), the BNF/BNF for Children (https://www.medicinescomplete.com/mc/index.htm)

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.
- Pregnant women, or women of childbearing potential who are not using reliable contraception during treatment with sulfasalazine and thereafter. **Note:** Pregnancy must be excluded before start of treatment with sulfasalazine.
- Porphyria.

PREGNANCY

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 can be continued with adequate folate supplementation at 5mg daily. Due to the folate depleting action of sulfasalazine primary care should prescribe 5mg daily folic acid for all women planning a pregnancy on sulfasalazine, ideally 4 weeks before conceiving.

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 outwith the product licensed which states patients should avoid breastfeeding while taking this medicine, but supported by specialist services.

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

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

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

- Live vaccines should be avoided in patients taking sulfasalazine.
- Some important interactions to consider include the following:
  - Sulfasalazine administered concurrently with digoxin can result in reduced absorption and non-therapeutic serum levels.
  - 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.
- 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.

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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