Rheumatology

Sulfasalazine Enteric Coated Tablets

(Salazopyrin EN-Tabs®)

Produced by The 3T's formulary

Further copies can be obtained from:
Pharmacy Department, Great Western Hospital
NHS Wiltshire

Addressograph label

Patient's Name _____

Consultant Name _____

Consultant Signature _____

Date _____

I agree to your request to prescribe Sulfasalazine Enteric Coated Tablets in accordance with the attached shared care guideline:

GP Name _____

GP Signature _____

Date _____

Sulfasalazine Enteric Coated Tablets

(Salazopyrin EN-Tabs®) (TLS Amber)

for the treatment of rheumatoid arthritis, psoriatic arthritis and sero-negative arthritis

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing Sulfasalazine Enteric Coated Tablets might be shared between specialist and general practitioner (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 such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, 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 is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes this medication legally assumes clinical responsibility for Sulfasalazine Enteric Coated Tablets and the consequences of its use.

RESPONSIBILITIES and ROLES

	Specialist responsibilities
1	Complete initial FBC, LFT and renal function tests.
2	Initiate treatment and prescribe escalation dose for at least one month.
3	Discuss the benefits and side effects of treatment with the patient, including reporting immediately any signs of bone marrow suppression (bleeding/bruising etc).
4	Ensure compatibility of sulfasalazine with other concomitant medication.
5	Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient & obtain their consent.
6	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
7	Review the patient's condition and monitor response to treatment at least annually or as deemed clinically necessary.
8	Give advice to the GP on future monitoring, dosage adjustment and when to stop treatment.
9	Report adverse events to the MHRA & GP.
10	Ensure that clear backup arrangements exist for GPs to obtain additional advice and support should they need it.

	General Practitioner responsibilities
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose recommended by the specialist
3	Ensure compatibility of sulfasalazine with other concomitant medication.
4	Undertake monitoring as per schedule on page 4 and refer to the specialist for advice on dosage adjustment.
5	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
6	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
7	Stop treatment on the advice of the specialist.
8	Report adverse events to the specialist and MHRA.

	Patient's role
1	Attend all appointments with GP and specialist, including appointments for blood tests and other monitoring.
2	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3	Share any concerns in relation to treatment with medicine.
4	Inform specialist or GP of any other medication being taken, including over-the-counter products.
5	Report any adverse effects to the specialist or GP whilst taking the medicine.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Email address:
Specialist (Rheumatology):			
Dr E Price – Consultant Rheumatologist	01793 604314	2112	Elizabeth.Price@gwh.nhs.uk
Dr L Williamson – Consultant Rheumatologist	01793 604318	1263	Lyn.Williamson@gwh.nhs.uk
Dr D Collins – Consultant Rheumatologist	01793 604317		David.Collins@gwh.nhs.uk
GWH Medicines Information	01793 605029		medinfo@gwh.nhs.uk
Rheumatology Team – Osprey Department	01793 604323		

SUPPORTING INFORMATION

Summary of condition/Licensed indications

- This guideline covers use in Rheumatoid arthritis, psoriatic arthritis* & sero-negative arthritis* (e/c tablets only).
- Use in Ulcerative colitis and Crohns Disease is **not** covered within this guideline. For details of dosing in these indications please contact the appropriate specialists.
- If used outside of these indications the specialist should liaise with the GP and provide background literature, before the appropriateness of a shared care agreement is assessed.

*unlicensed use in psoriatic arthritis and sero-negative arthritis

Expected / established place in local treatment pathway

Treatment of arthritis which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs.)
Aim of treatment is to prevent damage to joints and slowly reduce joint swelling and stiffness.

Dosage and administration

Rheumatoid arthritis and related conditions:

- Starting dose is 500mg OD increasing stepwise to 500mg QDS or 1g TDS, according to response and tolerance.
- Administer with or immediately after food.
- Tablets should not be crushed or broken.
- Therapeutic effect may only be evident after 6 weeks of treatment. If no improvement within six months consider additional agents.
- More cost effective to prescribe as Salazopyrin EN Tablets.

Contra-indications and precautions for use

- Contraindicated in known hypersensitivity to sulfasalazine, metabolites of sulfasalazine or any of the excipients.
- Contraindicated in children under 2 years of age
- Contraindicated in patients with porphyria
- Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency
- Use with caution in patients with severe allergies or bronchial asthma
- Sulfasalazine should not be used in patients with impaired hepatic or renal function or with blood dyscrasias unless benefit outweighs risk.

See SPC for full list of contraindications and precautions for use.

Side-effects

If a patient is going to experience an adverse effect with sulfasalazine it will often occur within the first six weeks of treatment

Very Common	Nausea, gastric upset
Common	Leucopenia, insomnia, taste disorders, tinnitus, headache, dizziness, conjuctival & sclera injection, cough, pruritis, rash, proteinuria, fever
Uncommon	Thrombocytopenia, depression, vertigo, dysponea, alopecia, urticaria, facial oedema, elevation of liver enzymes

Reversible oligospermia is also seen.
May colour urine & other secretions orange.
May stain soft contact lenses.

Please note that the following convention has been used for the classification of side-effects: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1000) and very rare (<1/10,000).

Refer patient back to the specialist if any of these side-effects cause concern. Refer to the SPC for a full list of adverse effects & further information http://www.medicines.org.uk.

This medicine does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.

Monitoring

Parameter	Frequency of monitoring	Action (adjustment and referral back to hospital)
Full Blood Count (incl. differential white cell count), liver function tests and assessment of renal function (incl. urinalysis)	Before initiation of treatment and monthly during the first 3 months of therapy, thereafter monitoring should be completed as clinically indicated but normally at least every 3-6 months.	If new fall below normal range or persistent downward trend

Drug Interactions

- Reduces absorption of digoxin resulting in non-therapeutic serum levels
- Hypoglycaemia has occurred in patients receiving sulphonamides
- Patients receiving hypoglycaemic agents should be closely monitored
- Care needed when co-prescribing with agents that affect the bone marrow.

See SPC for full list interactions

Cost

Salazopyrin EN Tablets 500mg x 112: £8.43

(NHS Prescription Services 12/06/2012)

References

Electronic Medicines Compendium. Summary of Product Characteristics. Salazopyrin EN Tablets (Sulfazalazine EC Tablets)

http://www.medicines.org.uk/EMC/medicine/10722/SPC/Salazopyrin+En-Tabs

Author

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