Effective Shared Care Agreement (ESCA)

Sulfasalazine enteric coated

ESCA: For the treatment of rheumatoid arthritis or psoriatic arthritis

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 **enteric coated** for rheumatoid arthritis or psoriatic arthritis can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are 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.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with rheumatoid arthritis or psoriatic arthritis are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of rheumatoid arthritis or psoriatic arthritis
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
4. Do baseline monitoring prior to initiation of sulfasalazine **enteric coated**
5. Initiate treatment and stabilise dose of sulfasalazine **enteric coated**
6. Review the patient's condition and monitor response to treatment regularly
7. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
8. Report serious adverse events to the MHRA
9. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days						
2. Prescribe sulfasalazine **enteric coated** at the dose recommended						
3. In the patient's notes, using the appropriate read code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment						
6. Refer back to specialist if condition deteriorates						
7. Report serious adverse events to specialist and MHRA						
8. Stop treatment on advice of specialist						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Share any concerns in relation to treatment with sulfasalazine **enteric coated** with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking sulfasalazine **enteric coated**
4. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td colspan="2">Treatment of rheumatoid arthritis which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs)</td></tr>
<tr><td>Dosage and Administration</td><td colspan="2"><table>
<tr><td>Preparation</td><td>Enteric Coated tablets improve gastrointestinal tolerability</td></tr>
<tr><td>BSR recommendation</td><td>Typical dose: 500 mg/day increasing by 500 mg weekly to 2.0–3.0 g/day. Occasionally doses above 3.0 g/day are prescribed</td></tr>
<tr><td>Suggested regimen</td><td>• 500 mg daily for first week
• 500 mg bd for second week
• 1 g mane 500 mg nocte for third week
• Then 1 g bd maintenance dose</td></tr>
<tr><td>Inadequate response on 2 g</td><td>Increase to 3 g per day in divided doses</td></tr>
</table></td></tr>
<tr><td>Renal Impairment
Hepatic impairment</td><td colspan="2">Sulfasalazine enteric coated should not be given to patients with impaired hepatic or renal function or with blood dyscrasias, unless the potential benefit outweighs the risk</td></tr>
<tr><td>Contra-indications / Special precautions</td><td colspan="2">Contraindications
Infants under the age of 2 years.
Patients with a known hypersensitivity to sulfasalazine, its metabolites or any of the excipients as well as sulfonamides or salicylates.
Patients with porphyria.
Cautions
Complete blood counts, including differential white cell count and liver function tests, should be performed before starting sulfasalazine, and every second week during the first three months of therapy. During the second three months, the same tests should be done once monthly and thereafter once every three months, and as clinically indicated. Assessment of renal function (including urinalysis) should be performed in all patients initially and at least monthly for the first three months of treatment. Thereafter, monitoring should be performed as clinically indicated. The patient should also be counselled to report immediately with any sore throat, fever, malaise, pallor, purpura, jaundice or unexpected non-specific illness during sulfasalazine treatment, this may indicate myelosuppression, haemolysis or hepatoxicity. Treatment should be stopped immediately while awaiting the results of blood tests.

Sulfasalazine should not be given to patients with impaired hepatic or renal function or with blood dyscrasias, unless the potential benefit outweighs the risk.
Sulfasalazine should be given with caution to patients with severe allergy or bronchial asthma.
Use in children with the concomitant condition systemic onset juvenile rheumatoid arthritis may result in a serum sickness like reaction; therefore sulfasalazine is not recommended in these patients.
Since sulfasalazine may cause haemolytic anaemia, it should be used with caution in patients with G-6-PD deficiency.
Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency (see section 4.6), potentially resulting in serious blood disorders (e.g. macrocytosis and pancytopenia), this can be normalised by administration of folic acid or folinic acid (leucovorin).
Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment.
Oligospermia and infertility may occur in men treated with sulfasalazine. Discontinuation of the drug appears to reverse these effects within 2 to 3 months.</td></tr>
<tr><td rowspan="2">Side Effects</td><td>Common</td><td>Leucopenia, insomnia, dizziness, headache, taste disorders, tinnitus, conjuctivial and scleral injection, cough, abdominal pain, diarrhoea, vomiting, stomatitis, pruritus, arthralgia, proteinuria, fever</td></tr>
<tr><td>Very common</td><td>Gastric distress, nausea</td></tr>
</table>

Monitoring **Update the BSR with license**	**Licence recommendations**	Complete blood counts, including differential white cell count and liver function tests, should be performed before starting sulfasalazine, and every second week during the first three months of therapy. During the second three months, the same tests should be done once monthly and thereafter once every three months, and as clinically indicated. . Assessment of renal function (including urinalysis) should be performed in all patients initially and at least monthly for the first three months of treatment. Thereafter, monitoring should be performed as clinically indicated. The patient should also be counselled to report immediately with any sore throat, fever, malaise, pallor, purpura, jaundice or unexpected non-specific illness during sulfasalazine treatment, this may indicate myelosuppression, haemolysis or hepatoxicity. Treatment should be stopped immediately while awaiting the results of blood tests.
	BSR recommendations	
	Pretreatment Assessment	Full blood count, urea and electrolytes, liver function tests, renal, C-reactive protein. Consider TMPT assay
	After commencing treatment	FBC and LFTs (including AST/ALT) monthly for the first 3 months and 3 monthly thereafter. If, following the first year, dose and blood results have been stable, frequency of blood tests can be reduced to every 6 months for the second year of treatment. Thereafter, monitoring of blood for toxicity may be discarded. Patient should be asked about the presence of rash or oral ulceration at each visit
	Actions to be taken	
	WBC<3.5x10^9/l	Withhold until discussed with specialist team
	Neutrophils<2.0x10^9/l	Withhold until discussed with specialist team
	Platelets<150x10^9/l	Withhold until discussed with specialist team
	AST, ALT>twice upper limit of reference range	Withhold until discussed with specialist team
	MCV>105 fl	Check B12, folate and TSH. If abnormal, treat any underlying abnormality. If normal, discuss with the specialist team.
	Nausea/dizziness/head ache	If possible continue, may have to reduce dose or stop if symptoms severe. Discuss with specialist team
	Abnormal bruising or severe sore throat	Check FBC immediately and withhold until results available. Discuss with the specialist team, if necessary
	Unexplained acute widespread rash	Withhold seek urgent specialist (preferably dermatological) advice.
	Oral ulceration	Withhold until discussed with specialist team.
	Disease monitoring	Occasional ESR/CRP helps assessment
	Cessation of treatment (seek advice)	• Platelets <120.000 • WBC <3.5 N <2.0 • LFTs 2x upper normal limit
	Dose reduction	Side effects:- nausea, diarrhoea rash, recurrent infection
Drug Interactions	Digoxin	Possible reduced absorption of digoxin
	Azathioprine	May contribute to bone marrow toxicity

References

- British Society for Rheumatology (BSR) guidelines
- SmPC Salazopyrin En Tablets
- Sulfasalazine BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with sulfasalazine **enteric coated** for rheumatoid arthritis or psoriatic arthritis

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: