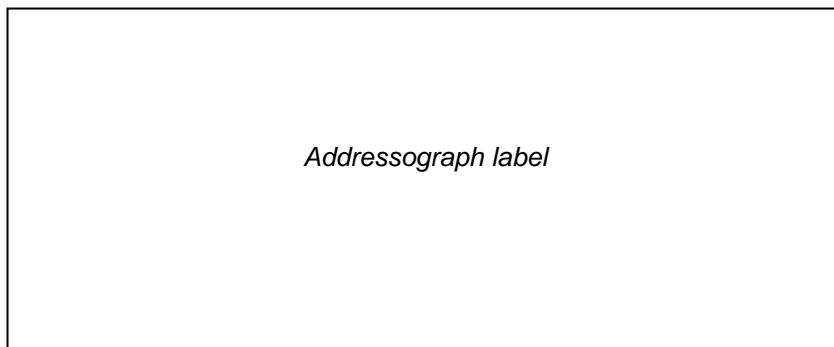


Further copies can be obtained from:

Pharmacy Department, Great Western Hospital  
NHS Wiltshire



**Patient's Name** \_\_\_\_\_

**Consultant Name** \_\_\_\_\_

**Consultant Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

**I agree to your request to prescribe Leflunomide in accordance with the attached shared care guideline:**

**GP Name** \_\_\_\_\_

**GP Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

# Leflunomide Tablets (*Arava*<sup>®</sup>) (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 leflunomide 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 leflunomide tablets and the consequences of its use.

## RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate and prescribe first two months of treatment.
2	Discuss the benefits and side effects of treatment with the patient.
3	Emphasise the importance of regular monitoring.
4	Ensure compatibility of leflunomide 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 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 leflunomide with other concomitant medication.
4	Undertake monitoring as per schedule on page 4.
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 monitoring and blood tests.
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	<a href="mailto:Elizabeth.Price@gwh.nhs.uk">Elizabeth.Price@gwh.nhs.uk</a>
Dr L Williamson – Consultant Rheumatologist	01793 604318	1263	<a href="mailto:Lyn.Williamson@gwh.nhs.uk">Lyn.Williamson@gwh.nhs.uk</a>
Dr D Collins – Consultant Rheumatologist	01793 604317		<a href="mailto:David.Collins@gwh.nhs.uk">David.Collins@gwh.nhs.uk</a>
GWH Medicines Information	01793 605029		<a href="mailto:medinfo@gwh.nhs.uk">medinfo@gwh.nhs.uk</a>
Rheumatology Team – Osprey Department	01793 604323		

**SUPPORTING INFORMATION****Summary of condition/Licensed indications**

As disease modifying therapy in Rheumatoid Arthritis, psoriatic arthritis and sero-negative arthritis\* in patients who have failed with adequate therapeutic trials of methotrexate or sulfasalazine. It is recommended as a trial **before** ciclosporin or Tumour Necrosis factor (TNF) inhibitors in suitable patients.

\*Unlicensed for use in sero-negative arthritis

**Dosage and administration**

Usual starting dose is 20mg/day

Recommended maintenance dose is 10-20mg once daily, depending on side effects experienced.

Therapeutic effect usually starts after 4-6 weeks of treatment and further improvements may be seen up to 4-6 months.

No dose adjustment is necessary in patients over 65.

Tablets should be swallowed whole with water.

**Contra-indications** (See SPC for full list of contra-indications and precautions)

- Hypersensitivity to leflunomide or any of the excipients
- Not recommended for use in patients under 18 years of age
- Impaired liver function
- Severe immunodeficiency (e.g. AIDS)
- Significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia due to causes other than rheumatoid or psoriatic arthritis
- Serious infections
- Moderate to severe renal insufficiency. No dose adjustment is required for patients with mild renal insufficiency.
- Severe hypoproteinaemia (e.g. in nephrotic syndrome)
- Pregnant women or women of child-bearing potential not who are not using reliable contraception during treatment
- Breast-feeding

**Precautions for use**

- Avoid alcohol consumption

**Side-effects**

Common	Mild increase in blood pressure, diarrhoea, leucopenia, vomiting, tenosynovitis, headache, mild allergic reactions, diarrhoea, abdominal pain, rash, raised LFTs, dizziness, nausea, hair loss, pruritis
Uncommon	Anaemia, hypokalemia, hyposphosphataemia, mild thrombocytopenia, hyperlipidemia, anxiety, urticaria, taste disturbances
Rare	Severe infection

*Please note that the following convention has been used for the classification of side-effects: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  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)
Alanine aminotransferase (ALT) or serum glutamopyruvate transferase (SGPT)	Before treatment initiation and monthly for the first 6 months	If three times upper limit of normal discontinue treatment, refer to specialist
A complete blood cell count, including a differential white blood cell count and a platelet count		If new fall below normal range or persistent decrease - discontinue treatment, refer to specialist
Blood Pressure	Before treatment initiation and periodically thereafter	Normal treatment

**Drug Interactions**

- Caution when prescribed with phenytoin, warfarin, phenprocoumon and tolbutamide.
- **Rifampicin** can increase levels of the active metabolites of leflunomide and should be avoided.
- Vaccination with live vaccines is **NOT** recommended.
- Avoid cholestyramine (except as wash out) as it speeds up elimination.

See SPC for full list of drug interactions

**Cost:** 30 tablets

10mg - £45.84

20mg - £54.70

(NHS Prescription Services 12/06/2012)

**References**

Electronic Medicines Compendium. Summary of Product Characteristics. Arava Tablets (Leflunomide)

<http://www.medicines.org.uk/EMC/medicine/7480/SPC/Arava+10%2c+20+and+100mg+Tablets/>

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**Date written:** November 2012

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