South West Yorkshire Area Prescribing Committee

LEFLUNOMIDE - Shared Care Guideline

Introduction	
General Statements	• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and GP. • The GP must reply in writing to the request for shared care as soon as practicable if unwilling to participate. • Responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and GP notes. • The agreement to consider the use of a shared care guideline should only be considered when the patient's clinical condition is stable or predictable.
Indication	Licensed: adults>18 years – rheumatoid arthritis, psoriatic arthritis

Individual's Responsibilities	
Hospital Specialist's Responsibilities	➢ Baseline monitoring and initial prescribing until the patient is established on treatment (minimum of 8 weeks). ➢ Monitoring disease progression and treatment response ➢ Supporting and advising GPs ➢ Monitoring booklets are available and may be beneficial in certain circumstances, for example if the patient receives blood monitoring at a location where results are inaccessible to the clinician. In these situations the Hospital Specialist will communicate this fact to the GP at the point when prescribing and monitoring is transferred ➢ Ensure that the patient has an adequate supply of medication until GP supply can be arranged. ➢ Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP. ➢ Provide patient with rheumatology nurse helpline contact number.
General Practitioner's Responsibilities	➢ Ensure hospital is notified if unwilling to undertake prescribing and monitoring when requested ➢ Prescribing following written request from specialist care ➢ Ensure monitoring is undertaken according to shared care guideline and only continue prescription if compliance with monitoring and results satisfactory. ➢ Follow guidance in the event of reaction or abnormality, record it and report back to the specialist ➢ Update patient's monitoring booklet as appropriate (including test dates & results, when available) ➢ Encourage influenza and pneumococcal vaccination as per Green Book ➢ Ensure no drug interactions with concomitant medicines ➢ To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring.
Monitoring Required	**Baseline** - FBC, U&E, Creatinine, LFT, blood pressure and weight Consider pregnancy test Consider Chest X-Ray and PFTs

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	The Hospital Specialist must confirm to the GP which stages of the maintenance monitoring have already been completed at the point when prescribing and monitoring are transferred to the GP **Maintenance -** FBC, LFTs, BP 2 weekly for 8 weeks, monthly for 4 months then 3 monthly
Information given to the patient	Patient information leaflet and monitoring booklet (provided by hospital specialist)
When and How to Discontinue Treatment	Loss of efficacy, intolerability, excessive weight loss, uncontrolled hypertension, abnormal blood monitoring. Please see overleaf for detailed guidance as regards stopping treatment. **Liaise with specialist care as washout procedure may be required.**
Contact Details	Documented in letter from specialist care to GP

Product Information	
The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics	
Dosage	Starting dose 10-20mg once daily (the licensed dose of 100mg once daily for 3 days is NOT recommended) Usual maintenance dose **10-20mg once daily**
Adverse Effects	Potential life threatening hepatotoxicity, usually in first 6 months. See table (page 2) Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Precautions and Contra-indications	Contraindications • Patients with hepatic disease or excess alcohol consumption. • It is recommended that patients treated with leflunomide avoid alcohol consumption • Pregnancy – **severe teratogenic risk** - ensure contraception during treatment and for 2 years after **discontinuation in** females, at least 3 months in males. Washout can be given to aid drug elimination. • Breast feeding is not recommended • Patients with moderate to severe renal insufficiency (due to lack of data) • Patients with severe hypoproteinaemia (e.g. in nephritic syndrome) **Washout procedure** – used in event of serious adverse effect, when drug elimination required prior to commencing alternative DMARD or prior to conception. Full details may be found in the Summary of Product Characteristics at www.medicines.org.uk/emc Contains lactose and soya lecithin – should not be used in patients with lactose, soya or peanut allergy. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Clinically relevant Drug Interactions and their management	**Avoid live vaccines** – examples could include oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster – for full details check the latest SPC before administration **Colestyramine, phenytoin, rifampicin, tolbutamide, warfarin.** Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.

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Recommended action for abnormal results

Investigation	Action
WBC <3.5 x10^9/L Neutrophils < 2 x10^9/L Platelets < 150 x10^9/L	Stop and contact specialist department
Hb fall >1g in 4 weeks or below 10g	Check for increased disease activity Ask about NSAID use and symptoms of GI blood loss or dyspepsia and stop NSAIDS if implicated. Check MCV and iron studies Consider endoscopy
ALT above normal range but below 3x upper limit --- ALT > 3x upper limit	Repeat bloods every 2 weeks Ask patient about viral/bacterial infections Check that it is not due to another drug or NSAID particularly diclofenac and stop this first Consider dose reduction to 10mg --- Stop and contact specialist department
Blood pressure >160/95, or significant rise	Treat hypertension but also contact specialist

Recommended action for adverse effects

Adverse event	Action
Bruising, bleeding	Check FBC and clotting screen
Itching	Reduce dose and review
Rash	Check for other causes e.g. complications of disease, vasculitis, steroid effects. Mild – reduce dose Severe – stop and contact specialist department as may require washout (risk of Stephen Johnson)
Alopecia	Reduce dose, stop if severe and contact specialist department
Oral ulcers, stomatitis	Check WBC Check for candida & treat accordingly. Mild- advise mouthwash and increased dental hygiene Severe – stop and contact specialist department
Weight loss >10% baseline	Stop and contact specialist department
Diarrhoea, abdominal pain, nausea	Check for other cause Mild -treat symptomatically & reduce dose if persistent. Stop if severe and contact specialist department.
New or increasing dyspnoea or persistent cough	Exclude infection and cardiac failure Stop and contact specialist department
Headache	Check for other causes Mild – try analgesia and reduce dose Severe - stop
Peripheral neuropathy	Stop and contact specialist