

Rheumatology Shared Care Guidelines

# Leflunomide

## Information sheet for GPs

Leflunomide is indicated for the treatment of adult patients with active rheumatoid arthritis as a “disease-modifying antirheumatic drug” (DMARD). Clinical improvement usually starts after 4 to 6 weeks. Further improvement may be seen after 4 to 6 months.

### Dose Regimen

- 100mg for 3 days followed by 20mg daily
- Dose can be reduced to 10mg daily if poorly tolerated.
- Recent treatment with hepatotoxic or haemotoxic DMARDs may result in increased side effects.
- A washout procedure should be performed when switching from leflunomide to another DMARD or in the case of a desired pregnancy, due to its long half life.

### Monitoring

- Baseline FBC, LFTs, U&E, and blood pressure
- FBC every two weeks for the first 6 months, then every 8 weeks thereafter.
- LFTs and blood pressure 4 weekly for the first 6 months, then every 8 weeks thereafter.
- Enter results in patient held record when shared care in place.

### Side Effects

- Gastrointestinal Disturbance  
(Abdominal pain, anorexia, nausea, vomiting, diarrhoea)

- Signs of Infection  
(in particular rhinitis, bronchitis, pneumonia)

- Rash, itch or oral ulceration
- WBC  $<4.0 \times 10^9/l$
- Neutrophils  $<2.0 \times 10^9/l$
- Platelets  $<150 \times 10^9/l$
- $>2$ -fold rise in AST, ALT, or ALP
- Increase in Blood Pressure

### Action

- 1.Continue if possible.
  - 2.If troublesome reduce dose from 20mg to 10mg daily
  - 3.d/w rheumatologist
- 1.Treat the infection - infections may be more severe and therefore require early and vigorous treatment
  2. If severe, withhold and d/w rheumatologist
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- In patients who become hypertensive, as defined by Royal College of Physician Guidelines, d/w rheumatologist

*Ask about side effects at every consultation.*

**Please note that in addition to absolute values for haematological indices a rapid fall or consistent downward trend in any values should prompt caution and extra vigilance**

### Absolute Contraindications

- Pregnancy, breast-feeding and women of child bearing potential not using reliable contraception.  
NOTE: Both men and women receiving leflunomide must use contraception throughout the treatment period, and for at least two years in women (3months men) after discontinuing treatment (until plasma levels have decreased to below 0.02 mg/l). Blood concentrations should be measured for the first time after the recommended waiting time and repeated after at least 14 days to ensure levels are below 0.02 mg/l before pregnancy occurs.
- Live Vaccines (oral polio, measles, mumps, rubella, BCG, oral typhoid, yellow fever) must not be administered whilst taking leflunomide.
- Moderate to severe renal insufficiency
- Severe hypoproteinaemia or impaired liver function

### Drug (and Non Drug) Interactions

- Leflunomide should not be used in conjunction with other DMARDs in routine clinical practice
- Leflunomide may inhibit the metabolism of warfarin, phenytoin and tolbutamide
- Alcohol should be avoided during treatment with leflunomide

#### References

SPC (Arava Tablets, Hoechst Marion Roussel Ltd), Mar 2001  
BSR Guidelines, July 2000

#### Authors

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Please consult the manufacturers Data Sheet or Summary of Product Characteristics for further information.

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