

<Insert name and address>

Leflunomide Winthrop - Risk minimisation resources to assist healthcare professionals

Dear Healthcare provider

May 2011

As part of the European marketing authorisation for *Leflunomide Winthrop (leflunomide) 10 mg film-coated tablets and 20 mg film-coated tablet*, Winthrop Pharmaceuticals UK Limited (trading as Zentiva) has developed the enclosed documents for health care professionals to assist in the management of important risks associated with the use of leflunomide.

Healthcare professionals and patients should familiarise themselves with the measures that should be taken to minimise the risks of hepatic and haematological reactions, interactions with other DMARDs, infections and teratogenicity, and the contraindications when prescribing, dispensing or using *Leflunomide Winthrop*.

Please find enclosed:

- A Safety Information leaflet which lists the most important risks you should be aware of when prescribing *Leflunomide Winthrop*
- A Patient Information sheet developed for distribution to patients
- Copies of the current approved *Leflunomide Winthrop* Summary of Product Characteristics (SmPC)

#### **Call for Reporting**

Please remember that any suspected adverse reaction associated with the use of *Leflunomide Winthrop* should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card Scheme online at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

Alternatively, prepaid Yellow Cards for reporting are available:

upon request by mail: "FREEPOST YELLOW CARD"

at the back of the British National Formulary (BNF)

by telephoning the Commission on Human Medicines (CHM) free phone line:  
0800-731-6789

Or by electronic download through the MHRA website  
(<http://yellowcard.mhra.gov.uk/downloads/>)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

In addition, suspected adverse drug reactions may be reported to the sanofi-aventis UK Pharmacovigilance department at:

Sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Tel: 01483 554242

Fax: 01483 554806

E-mail: [uk-drugsafety@sanofi-aventis.com](mailto:uk-drugsafety@sanofi-aventis.com)

**Communication information:**

Should you have any questions or require further information regarding *Leflunomide Winthrop* please also contact our Medical Information department at:

Zentiva Medical Information Department

One Onslow Street, Guildford, Surrey, GU1 4YS, UK

Tel: 01483 505515

Fax: 01483 535432

E-mail: [uk-medicalinformation@sanofi-aventis.com](mailto:uk-medicalinformation@sanofi-aventis.com)

The content of this letter has been agreed with the MHRA.

Yours sincerely



**Dr Tony Whitehead**  
UK Medical Director