



# DRUG ALERT

## CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use  
Distribute to Pharmacy Level

Date: 03 Jan 2017

EL (17)A/01

Our Ref: MDR 118-11/16

Dear Healthcare Professional,

**Sanofi-Aventis Deutschland GmbH**

**Arava 10mg film-coated tablets  
(Leflunomide)**

**EU/1/99/118/003**

Batch Number	Expiry Date	Pack Size	First Distributed
5JK2A	Nov 2018	1 x 30	16 May 2016
5JK3A	Dec 2018	1 x 30	08 Aug 2016
5JK6G	Jan 2019	1 x 30	12 Sep 2016
6EV2A	May 2019	1 x 30	25 Oct 2016

Sanofi on behalf of Sanofi-Aventis Deutschland GmbH, has informed us that there is an error in the Braille on 1 in 5 cartons from the above batches. On affected cartons, the strength of the product reads '20mg' instead of '10mg' in Braille. The printed text is correct on all packaging.

There is a risk to patients who have compromised eye-sight and who rely solely on Braille to determine their tablet strength. **Packs with the above batch numbers should not be dispensed to patients who rely solely on Braille.** We understand that there is an alternative batch available, batch number 6GL5E, expiry Aug 2019. If your wholesaler does not have this batch in stock, please contact Sanofi Customer Services on 0800 854 430

For medical information enquiries, please contact Sanofi Medical Information department on 0845 3727101 or email [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to relevant clinics, dispensing GPs and community pharmacists for information.

Yours faithfully

Alison Bunce

**Pharmaceutical Assessor  
Defective Medicines Report Centre  
151 Buckingham Palace Road  
London  
SW1W 9SZ  
Telephone +44 (0)20 3080 6574**