Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 16 October 2019 EL (19)A/25 Our Ref: MDR 127-09/19

Dear Healthcare Professional,

Aventis Pharma Limited t/a Sanofi

Rifadin (rifampicin) 150mg Capsules PL 04425/5915R

Batch Number	Expiry Date	Pack Size	First Distributed
9G020A	12/2021	1 x 100	16 October 2019

Brief description of the problem
Sanofi has informed us that a change to the Patient Information Leaflet (PIL) for this product has not been implemented by the required timeline. The change concerns:

- The addition of possible side effect, 'Acute Generalized Exanthematous Pustulosis (AGEP)' - a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment
- The addition of possible side effect, 'risk of severe bleeding'
- The addition of Drug-Drug interactions with Hepatitis C drugs, including indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, neviparine, daclatasvir, simeprevir, sofosbuvir and telaprevir

It is important that any patients who notice the symptoms seek immediate medical advice.

Advice for healthcare professionals

When dispensing this product, please check the Marketing Authorisation Holder and the batch number. If any of the above batch numbers are being dispensed, please remove the PIL in the pack and provide a copy of the correct version, which can be downloaded from the link below:

https://www.medicines.org.uk/emc/product/6382/pil

Further Information
For medical information enquiries, please contact Sanofi Medical Information,
Tel +44 (0) 845 372 7101; email 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 community pharmacists and dispensing general practitioners for information.

Yours faithfully

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