

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

#### Caution in Use

#### Distribute to Pharmacy Level

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, nevirapine, 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](mailto:uk-medicalinformation@sanofi.com).

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

### **TO ALL CHEMISTS, DOCTORS ON THE LISTS**

Pharmaceutical Services  
2 Franklin Street  
BELFAST  
BT2 8DQ

Telephone No. 028 9536 0333

**16<sup>th</sup> October 2019**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>