

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	16 October 2019
Reference:	CEM/CPhA/2019/25
Category:	Class 4: For Information
Title:	Class 4 Drug Alert, For Information / Action, Aventis Pharma Limited T/A Sanofi, Rifadin (Rifampicin) 150mg Capsules
For Action by:	<p>Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'</p> <p>Community Pharmacists</p> <p>Hospital pharmacies</p> <p>Chief Pharmacists</p>
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

Sanofi has informed us that a change to the Patient Information Leaflet (PIL) for Rifadin (rifampicin) 150mg Capsules has not been implemented by the required timeline. For the affected batch (9G020A) healthcare professionals are asked to remove the PIL in the pack and provide a copy of the correct version, which can be downloaded from the following link <https://www.medicines.org.uk/emc/product/6382/pil>.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>.

Appendix 1

To: Chief Executives of Health Boards and NHS Trusts
To: Medical Directors of Health Boards
To: Nurse Directors Health Boards
To: Directors of Public Health
To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

Dispensing General Practitioners

Community Pharmacists

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales



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, 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.

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.



Medicines & Healthcare products
Regulatory Agency



Yours faithfully

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