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sanofi-aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24

Important information for healthcare professionals

Update to Rifampicin & Rifampicin combination Product Information regarding potential genotoxicity and associated contraceptive requirements

Rifampicin:

Rifadin 150 mg Capsules PA 540/66/1

Rifadin 300 mg Capsules PA 540/66/2

Rifadin Intravenous 600mg Powder and Solvent for Concentrate for Solution for Infusion PA 540/66/3

Rifadin 100mg/5ml Oral Suspension PA 540/66/4

Rifampicin/Isoniazid:

Rifinah 150/100mg Film-coated Tablets PA 540/68/1

Rifinah 300/150mg Film-coated Tablets PA 540/68/2

Rifampicin/Isoniazid/Pyrazinamide:

Rifater 50mg/300mg/120mg Tablets PA 540/67/1

Dear Healthcare Professional

The Rifampicin product range are approved for use in Ireland in the following indications:

Rifadin (Rifampicin):

- in combination with other active anti-tuberculosis drugs, is indicated in the treatment of tuberculosis and certain mycobacterial infections
- Rifadin is active in vitro at low concentrations against Gram-positive organisms and N. Gonorrhoea.

Rifinah (Rifampicin/Isoniazid):

- in the treatment of tuberculosis, and other mycobacterial infections.

Rifater (Rifampicin/Isoniazid/Pyrazinamide):

- in the treatment of pulmonary tuberculosis.



Background on the safety concern

The product information for the Rifampicin product range has been updated regarding potential genotoxicity, based on non-clinical data. Consequently sections 4.4, 4.6 and 5.3 of the SmPC and corresponding sections of the Patient Leaflet have been updated. A summary of these updates is provided below:

Summary

- Due to the genotoxic potential of rifampicin, contraception is advised in males and females, during and after treatment.
- Male patients with female partners of reproductive potential should be advised to use a condom plus an additional contraceptive method that together are highly effective during treatment and for 3 months after the last dose.
- Female patients of childbearing potential should be advised to use highly effective non-hormonal contraception during treatment and for 6 months after the last dose.
- Due to interaction between rifampicin and hormonal contraceptives, female patients using systemic hormonal contraceptives should be advised to change to non-hormonal methods of birth control.
- For female patients of childbearing potential, pregnancy testing should be performed prior to treatment.
- Non-clinical safety data regarding potential genotoxicity is available in Section 5.3 of the SmPC.

The Summary of Product Characteristics (SmPC) and Patient Information Leaflet containing the updated information are available on the HPRA website www.hpra.ie.

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated accordingly.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie. Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com

Company contact point

Should you have any questions or require additional information, please contact Medical Information Department at IEmedinfo@sanofi.com or by phone on 01 403 5600.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Khizer Jehangir".

Khizer Jehangir

Medical Head – Established and Legacy Portfolio Products, Sanofi UK & Ireland