

Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 6th May 2016

Our Ref: MDR 08-05/16

Dear Healthcare Professional,
Sanofi c/o Charles de Giorgio Ltd.

Rifadin 600mg powder and solvent for solution for injection
(rifampicin)

MA 082/02401

Batch Number	Expiry Date	Pack Size	First Distributed
A5545	September 2019	1 vial and 1 solvent	February 2016

The Medicines Authority has been notified by Sanofi Malta that Rifadin 600mg freeze dried product for injection with batch number A5545 is being voluntarily recalled up to hospital level.

The reason for the recall is the presence of unexpected chemical compound in the product, due to a technical issue on a compounding vessel during the manufacturing process.

Affected stock is to be quarantined till the supplier collects the recalled product.

Yours faithfully

Muriel Giglio
Medicines Inspector