

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 22nd February 2016

Our Ref: MDR 04-02/2016

Dear Healthcare Professional,

Sanofi Malta Ltd.

3rd Floor, Avantech Building, St. Julian`s Road
San Gwann SGN 2805
Malta

Palgotal 75mg/650mg film-coated tablets
(Tramadol hydrochloride/Paracetamol)

MA082/07701

Batch Number	Expiry Date	Pack Size	First Distributed
2021014	September 2016	x30	19 th June 2015

Under the supervision of the Medicines Authority, Sanofi Malta Ltd. (the Marketing Authorisation Holder: MAH) in collaboration with Charles de Giorgio Ltd. (the local distributor) is recalling Palgotal 75mg/650mg film-coated tablets (Tramadol hydrochloride/Paracetamol), batch number **2021014** up to pharmacy level.

The Medicines Authority has been notified by a pharmacy that Palgotal 75mg/650mg film-coated tablets (B.N.: **2021014**) available on the local market has been mislabelled as a medicinal product not requiring a medical prescription, even though this product is a Prescription Only Medicine (POM) item.

Wholesale dealers and pharmacies are asked to quarantine all stock of the above product with batch number **2021014**.

Yours faithfully,

Judit FEHÉR
Medicines Inspector