

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 15th January 2016

Our Ref: MDR07-01/16

Dear Healthcare Professional,

SOFAR S.p.A, Italy

c/o Pharma-Cos Ltd, Malta

**Pentacol 400mg gastroresistant modified-release
tablets
(mesalazine)**

MA133/00201

Batch Number	Expiry Date	Pack Size	First Distributed
V0175	03/2017	60 tablets	23.04.15
V0176	03/2017	60 tablets	23.04.15
V0177	03/2017	60 tablets	23.04.15

Following the notification of a defect and subsequent investigation requested by the Medicines Authority, the above product batches are being recalled up to pharmacy level under the supervision of the same Medicines Authority by the Marketing Authorisation Holder, SOFAR S.p.A c/o Pharma-Cos Ltd.

The batches are being recalled since the manufacturer has confirmed that the said batches may be subject to capping and/or cracked gastro-resistant coating.

Wholesale dealers and pharmacies are asked to quarantine all stock of the above product and await instructions by Pharma-Cos Ltd which is responsible to recall the affected stock.

Yours faithfully

Karl De Marco
Medicines inspector

Medicines Authority Distribution (if applicable): None

203, Level 3, Rue D'Argens, Il-Gzira, GZR 1368, Malta
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt