

QD004/08 Appendix 01 Version01

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Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

MA133/00201

Date:7th July 21017

Our Ref: MDR 03-07/17

Dear Healthcare Professional,

SOFAR S.p.A, Italy

c/o Pharma-Cos Ltd, Malta

Pentacol 400mg gastroresistant modifiedrelease tablets

(mesalazine)

 Batch Number
 Expiry Date
 Pack Size
 First Distributed

 V0525
 08/2017
 60 tablets
 October 2015

Following the notification of a defect, the Medicines Authority has instructed this Class II recall up to pharmacy level.

The batches are being recalled since 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 who is responsible to recall the affected stock.

Yours faithfully

Eloise Buontempo Medicines Inspector

