

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 22nd March 2016

Our Ref: MDR 18-03/16

Dear Healthcare Professional,

Neofarma Ltd.

Motilium Oral Suspension 1mg/ml
Domperidone

PI908/04802A

Batch Number	Expiry Date	Pack Size	First Distributed
FIB2700	08/2018	1	17 th February 2016
FIB2800	08/2018	1	11 th March 2016

Following the notification of a defect by the Marketing Authorisation Holder (MAH), the above product batches are being recalled up to pharmacy level by the MAH Neofarma Ltd. under the supervision of the Medicines Authority.

The batches are being recalled due to a defect in the Patient Information Leaflet (the leaflet is only in French and not in an official language).

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

Yours faithfully,

Clint Pace
Medicines Inspector

Medicines Authority Distribution (if applicable):
Licensing Authority
Superintendent of Public Health