

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 13th October 2014

Our Ref: MDR 4-10/14

Dear Healthcare Professional,

Leo Pharmaceuticals

c/o PHARMA-COS LTD.

Burinex Injections

MA024/00602

(2mg/ampoule bumetanide)

Batch Number	Expiry Date	Pack Size	First Distributed
F1006MT1	01/2016	carton x 5 ampoules of 4ml	04.06.2013
F1007MT1	06/2016	carton x 5 ampoules of 4ml	14.08.2013
F1008MT1	09/2016	carton x 5 ampoules of 4ml	16.12.2013
F1009MT1	10/2016	carton x 5 ampoules of 4ml	16.12.2013
F1009MT2	10.2016	carton x 5 ampoules of 4ml	06.05.2014

Leo Pharmaceuticals

c/o Central Procurement and Supplies Unit

Batch Number	Expiry Date	Pack Size	First Distributed
F1006FP1	01/2016	carton x 5 ampoules of 4ml	22.10.2013

Kindly note that the following product batches are being recalled up to ward level under the supervision of the Medicines Authority, following a notification issued by the qualified person at the batch release site in the European Union declaring that the said batches may be subject to out-of-specification stability results.

Yours faithfully

Christopher Attard

Medicines Inspector