

Drug Alert

CLASS 2 MEDICINES RECALL Action Within 48 Hours

Date: 17th August 2015

Our Ref: MDR 10-8/15

Dear Healthcare Professional,

Novartis Consumer Health S.A. (a GSK Consumer Healthcare Company)

Otrivine 0.05% W/V nasal spray (Xylometazoline HCl 0.05%)

Batch Number	Expiry Date	Pack Size	First Distributed
All batches	N/A	x 1	N/A

The Medicines Authority has been notified by Associated Drug Co Ltd. – a local licensed wholesale dealer – that all the batches of the medicinal product Otrivine 0.05% w/v nasal spray have outer packaging inconsistancies in the Arabic language.

This recall is being classified as a Class II recall up to pharmacy level and is being carried out by Associated Drug Co Ltd. under the supervision of the Medicines Authority.

Yours faithfully

Christopher Attard Medicines Inspector Medicines Authority