

Drug Alert

CLASS III MEDICINES RECALL

Action Within 5 Days

Date: 30th October 2014

Our Ref: MDR 11-10/14

Dear Healthcare Professional,

Bruschettini S.r.l.

c/o AMAS Co LdLtd.

Rino-Naftazolina 0.2% Nasal Spray

MA016/00302

Batch Number	Expiry Date	Pack Size	First Distributed
32	04/2017	1	16 th June 2012
22	06/2018	1	8 th October 2012

Kindly note that the following product batches are being recalled up to pharmacy level under the supervision of the Medicines Authority, on instructions of the Italian Authority AIFA following and inspection of the manufacturing site. A renovated department has been used without prior authorization of AIFA (Italian Medicine Agency)

This recall does not affect any other batches or dosage forms.

In Malta, this recall is being carried out to pharmacy level by Amas Co. Ltd. under the supervision of the Medicines Authority.

Thank you for your cooperation. For any clarification, please do not hesitate to contact the undersigned.

Yours faithfully,

Christopher Attard

Medicines Inspector