

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 14 th August 2015	Our Ref: MDR 9-8/15

Dear Healthcare Professional,

GlaxoSmithKline Ltd (Malta)

Bactobran Nasal Ointment (MA447/00301) Bactroban Ointment(MA447/00302) Bactroban Cream(AA447/00303)

(Calcium mupirocin)

Batch Number	Expiry Date	Pack Size	First Distributed
C700830/C694256	N/A	x 1	N/A
(Bactroban Nasal)			
C703976/C725156	N/A	X 1	N/A
(Bactroban cream)			

The Medicines Authority has been notified by GlaxoSmithKline (Malta) Ltd. Distributor – Alfred Gera & Sons Ltd – a local licensed wholesale dealer – that all the batches listed in the table above of the medicinal product Bactroban Nasal Ointment and Bactroban Cream are being recalled due to the potential for physical contamination of Calcium Mupirocin API used. These particulates include glass and paint fragments from manufacturing equipment and fibres from cleaning materials and personnel clothing.

This recall is being classified as a Class II recall up to wholesaler level and is being carried out by Alfred Gera & Sons Ltd. under the supervision of the Medicines Authority.

Yours faithfully

Christopher Attard Medicines Inspector Medicines Authority