



Medicines Authority

**Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL

ACTION WITHIN 48 HOURS

Date: 14th July 2009

Our Ref: MDR 7/09

Dear Responsible person for Wholesale Dealer/Managing Pharmacist/General Public

Rhinathiol® (carbocisteine) 2% sugar free for children and infants - MA 082/05102

Batch Number	Expiry date	Pack size	First distributed
All batches	All batches	One pack size	Not applicable

The Inspectorate and Enforcement Directorate within the Medicines Authority received a Medicinal Defect Report warranting a recall.

The recall has been classified as a Class 2 recall up to patient level and is being carried out by Sanofi-Aventis Malta Ltd. (Marketing Authorisation Holder) in collaboration with Charles de Giorgio Ltd. (the local distributor of the Marketing Authorisation Holder) under the supervision of the Medicines Authority.

The reason for the recall of all batches of the product is possible microbial contamination since phenol was detected in one lot of the product due to degradation of the conservation agent (methyl-parabene).

Therefore patients will be notified by press release to return all Rhinathiol® 2% sugar free syrup to the pharmacy from where it was purchased.

All other presentations of Rhinathiol® (carbocisteine) on the local market are not affected.

Thanks and regards

Eloise Buontempo
Medicines Inspector