

Medicines Authority Inspectorate and Enforcement Division 203 Level 3, Rue d'Argens, Gzira Malta

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Drug Alert

CLASS 2 MEDICINES RECALL ACTION WITHIN 48 HOURS

Date: 14/07/2010

Our Ref: MDR 5_07/10

Dear Healthcare Professional,

Fucidin®(Sodium fusidate) Pdr for Soln for Infusion 500mg vials

Batch Number	Expiry Date
DC8315	05/2011
DD5430	01/2012

The Inspectorate and Enforcement Division within the Medicines Authority have been informed by the Danish Medicines Agency of a quality defect warranting a recall. This recall is being carried out by the Government Health Procurement Services (GHPS) in agreement with the Medicines Authority. It has been classified as a Class 2 recall up to hospital pharmacy level.

This recall was initiated after a number of glass vials were found to contain glass particles upon examination.

Simon Serge Medicines Inspector