



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

Telephone: +356 2343 9142

Facsimile: +356 2343 9162

Drug Alert

CLASS 2 MEDICINES RECALL ACTION WITHIN 48 HOURS

Date: 12/07/2010

Our Ref: MDR 5_07/10

Dear Healthcare Professional,

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

Batch Number	Expiry Date
DC1313	14.09.2010
DD9538	14.05.2012

The Inspectorate and Enforcement Division within the Medicines Authority have been informed by the Danish Medicines Agency of a medicinal defect warranting a recall. This recall is being carried out by Pharma-Cos Ltd. under the supervision of 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