



DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days

Wholesaler, Pharmacy and Hospital Pharmacy Level Recall

Date: 08 November 2016

EL (16)A/15

Our Ref: MDR 23-10/16

Dear Healthcare Professional,

Amdipharm UK Limited

Hydrocortisone 100mg/1ml Solution for Injection

PL 20072/0229

(Hydrocortisone Sodium Phosphate)

Batch Number	Expiry Date	Pack Size	First Distributed
039268	Aug 2017	1 x 5	27 May 2016

Concordia International (formerly AMCo) is recalling the above batch as a precaution following the receipt of a number of complaints that the solution in some ampoules has a yellowish appearance.

Investigation of affected samples has shown that all other analytical parameters, including assay and related substances, are met. A toxicological evaluation carried out by the company concluded that the discoloured ampoules pose no risk to patients. Some packs may contain one or more discoloured ampoules, however, and it is possible that the variance in colour may give rise to concern.

Remaining stock of this batch should be quarantined and returned to the original supplier for credit.

For stock enquiries please contact Concordia Customer Care Services on 08708 877025 or email customercare@concordiarx.com

For medical information enquiries please contact Concordia Medical Information on 08700 703033 or email <u>medicalinformation@concordiarx.com</u>

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams: please cascade to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

Alison Bunce Pharmaceutical Assessor Defective Medicines Report Centre 151 Buckingham Palace Road London SW1W 9SZ Telephone +44 (0)20 3080 657