

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 29 Apr 2013

EL 13(A)13

Our Ref: MDR 62-03/13

Dear Healthcare Professional,

Aurum Pharmaceuticals Limited (trading as Martindale Pharma)

Adrenaline (Epinephrine) Injection 1:10,000 1mg/10ml

PL 12064/0006

Amiodarone Injection 30mg/ml

PL 12064/0047

Ephedrine Hydrochloride Injection 3mg/ml

PL 12064/0043

Product Name	Batch Number Range From and to inclusive	Expiry Date Range From and to inclusive	First Distributed
Adrenaline 1mg/10ml	From 5000879 to 5000964	From 05/2014 to 07/2014	06 Feb 2013
Amiodarone 30mg/ml	From 5000610 to 5000870	From 02/2014 to 11/2014	28 Nov 2012
Ephedrine Hydrochloride 3mg/ml	From 5000452 to 5000846	From 09/2013 to 10/2014	22 Dec 2011

Aurum Pharmaceuticals Limited (trading as Martindale Pharma) has informed us that there is a misalignment of the syringe label of the above pre-filled syringe batches. The syringe label includes the graduated volume markings.

Pre Filled Syringes from the affected batches should be used with caution.



The syringe in the top position has the label in the correct position

The syringe in the lower position has the label applied too close to the end of the barrel and should be used with caution.

Contd/...

The implication of this misalignment is that incorrect dosing could occur if the entire contents of the syringe are not used. For example if a dose was titrated between the intermediate and completely empty position.

The fill-volume and total dose in the syringe is correct. It may appear that there is over-fill of the syringe. Do not discard what appears to be excess before administration.

This issue has been corrected by the manufacturer however this issue may be present within the market for a period of time.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Adam Burgess
Manager, DMRC

Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574