

Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
PATIENT LEVEL RECALL

Date: 23 May 2012

EL (12)A/20

Our Ref: MDR 23-04/12

Dear Healthcare Professional,

Lincoln Medical Limited

**Anapen 500 micrograms in 0.3ml solution
for injection in a pre - filled syringe** **PL 18813/0003**

**Anapen 300 micrograms in 0.3ml solution
for injection in a pre - filled syringe** **PL 18813/0001**

**Anapen Junior 150 micrograms in 0.3ml
solution for injection in a pre - filled syringe** **PL 18813/0002**
(Adrenaline (Epinephrine) autoinjector)

Lincoln Medical Limited is recalling all unexpired units of the above products **to patient level** as a precaution. This is because a potential problem with delivery time and delivery volume of the dosage following activation of the autoinjector has been identified during development work. In the worst case scenario, this could result in a failure to deliver any adrenaline at all in an emergency situation. The Company has informed us that they have received no defect or ADR reports from the market which may be associated with this issue.

Recipients are requested to contact any patients who may be holding units of these products and advise them to make an appointment with their GP or clinic to discuss switching to an alternative product as soon as possible.

Cont/.....

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)
151 Buckingham Palace Road London SW1W 9SZ UK
T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health



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Pharmacists are requested to return any unexpired stock via their normal wholesaler to UDG for credit. For medical information enquiries, please contact 'Professional Information' on 01748 828785

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics, General Practitioners and Community Pharmacists for information.

Yours faithfully

Alison Bunce
Pharmaceutical Assessor, DMRC