



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL ACTION WITHIN 48 HOURS

Date: 17/02/2010

Our Ref: MDR 5_02/10

Dear Healthcare Professional,

Citanest 1%® [Prilocaine Hydrochloride 10mg/ml] multi-dose vials (50ml)

Batch Number	Expiry Date	First Distributed
FP186	29.05.2011	27.02.2009
FJ545	26.03.2011	19.11.2008
FF738	14.12.2010	10.09.2008
FD238	11.12.2010	21.07.2008
FA944	05.09.2010	24.04.2008
EY517	28.08.2010	10.09.2008
EX030	25.07.2010	10.09.2008
EV050	02.05.2010	27.11.2007

The Inspectorate and Enforcement Division within the Medicines Authority have been informed by the UK Authority of a medicinal defect warranting a recall. This recall is being carried out by GHPS under the supervision of the Medicines Authority. It has been classified as a Class II recall up to pharmacy/ward level.

This recall was initiated following an out of specification during routine stability studies, indicating that the single preservative used in this product has the potential to fall below limits after 24 months. The product has a 36 month expiry date.

Batches which expire in 2012 are not being recalled at present.

Simon Serge
Medicines Inspector