



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS 2 MEDICINES RECALL

ACTION WITHIN 48 HOURS

Date: 29th September, 2006

Our Ref: MDR 3-9/06

Dear Managing Pharmacist

Cherubino Ltd., Malta

Roaccutane (Isotretinoine 20mg) tablets

MA 060/1203

Batch Number	Expiry date	Pack size	First distributed
B 3161	January 07	60 tablets	November 2004
B3429	November 07	30 tablets	April 2005
B3441	January 08	30 tablets	May 2005
B3445	January 08	30 tablets	June 2005

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed of a Medicinal Product Defect dated 26th September 2006 by Spanish Agency for Medicines & HealthCare Products. The reason for the defect is that some batches had out of specification tretinoin content in continuous stability tests carried out.

The recall is being carried out under the supervision of the Medicines Authority and has been classified as a Class 2 recall up to pharmacy level.

Thanks and regards

Mark Cilia
Medicines Inspector