

Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Clinic and Wholesaler Level Recall

Date: 05 March 2013

EL (13)A/08

Our Ref: MDR 01-01/13

Dear Healthcare Professional,

Mylan

Montelukast 5 mg Chewable Tablets

PL 04569/1143

Batch Number	Expiry Date	Pack Size	First Distributed
8009003	11/2014	1 x 28 tablets	25/02/2013

Mylan are recalling all remaining packs of the above batch to pharmacy, clinic and wholesaler level, due to an error on the carton. The carton incorrectly states "For children 2 to 5 years" but the patient information leaflet (PIL) correctly states "For children 6 to 14 years"

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Laura Ainslie on 01707 853006 or by email at laura.ainslie@mylan.co.uk, alternatively please contact Mylan Customer Services on 01707 853100 or email mguk_edi_orders@mylan.co.uk.

For medical information enquiries please contact Mylan Medical Information on 01707 853000 or email info@mylan.co.uk.

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

Adam Burgess

MHRA DMRC Manager

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)

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An executive agency of the Department of Health