

Safeguarding public health
Defective Medicines Report Centre
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MHRA

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
PHARMACY LEVEL RECALL

Date: 21 June 2011

EL (11)A/17

Our Ref: MDR 51-06/11

Dear Healthcare Professional,

Bayer plc, Consumer Care Division

Canesten Pessary, Legal status 'P'

PL 00010/0083

(Clotrimazole 500mg)

Batch Number	Expiry Date	Pack Size	First Distributed
BXFWKG1	31 Mar 2016	1x1	16 May 2011
BXFTDVI	31 Jan 2016	1x1	14 Jun 2011

Bayer plc, Consumer Care Division is recalling the above batches because they have inadvertently been placed on the market containing the Patient Information Leaflet (PIL) intended for the 'POM' product. The PIL for the 'P' pack includes additional safety warnings and precautions which are not present in the 'POM' leaflet. 'P' products are available in a pharmacy without prescription, under the supervision of a pharmacist, hence the requirement for additional safety information on the PIL.

Pharmacists are asked to quarantine any remaining stock of these batches and return it to the wholesaler from which it was originally obtained.

For stock enquires, please contact your wholesaler or original order point. For medical information enquiries please contact Bayer Medical Information on 01635 563232

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 community pharmacists.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC

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