

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists, NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG ALERTS NO 22 – CLASS 4

Please find attached revised drug safety information from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Directors of Pharmacy forward this alert to:-
 - Hospital pharmacists
 - Chief Pharmacists to forward on to Medicines Information Pharmacists
 - Community pharmacists
2. Please could Medical Directors forward the message on to :-
 - General Practitioners
 - Dispensing Doctors
 - Chief Executives NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy Division

* NB: Drug alerts have the following classifications:

1. Action now (including out-of-hours); 2. Action within 48 hours; 3. Action within 5 days; 4 Caution in use

Safeguarding public health
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
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Fax: +44 (0)20 7084 2676

DRUG ALERT
CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 14 July 2009

EL (09)A/22

Our Ref: MDR 09-07/09

Dear Healthcare Professional,

Solvay Healthcare Limited

Creon Micro Pancreatin 60.36mg Gastro-resistant Granules

PL 00512/0179

Batch Number	Expiry Date	Pack Size	First Distributed
44697	11/2010	20g	30 June 2009

Solvay Healthcare Limited has informed us that the lid on bottles of Creon Micro Pancreatin 60.36mg Gastro-resistant Granules from the above batch may spontaneously open, either fully or partially. The product is only affected once the tamper evident strip has been removed.

To avoid stock disruption, this batch is not being recalled. Solvay Healthcare Limited hope to have a new batch available during week commencing 03 August 2009. In the meantime, please inform recipients of this batch of the issue, including those patients who may already have received it.

Patients/carers are advised to tape the lid securely shut once the tamper evident strip is removed. For extra security, the whole bottle may be placed in a resealable plastic bag, although any granules which escape should be discarded. Once opened, product from this batch should only be used for 14 days. Solvay Healthcare Limited has informed us that they will provide any additional stock required due to this issue free of charge.

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
Market Towers 1 Nine Elms Lane London SW8 5NQ
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

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For further information please contact the Solvay Healthcare Limited Medical Information Unit on 02380 467000 or e-mail medinfo.shl@solvay.com.

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.

Yours faithfully

Alison Bunce
Pharmaceutical Assessor, DMRC