

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

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Dear Healthcare Professional,

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**DRUG ALERTS NO 28 Rev1 – CLASS 2**

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:-
  - Community Pharmacists
  - Hospital pharmacists
  - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward the message on to :-
  - General Practitioners
  - Dispensing Doctors
  - Relevant Clinics
  - 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**  
**Telephone: +44 (0)20 7084 2574**

**Fax: +44 (0)20 7084 2676**

**DRUG ALERT**

**CLASS 2 MEDICINES RECALL**

**Action Within 48 Hours**

**PHARMACY OR EQUIVALENT LEVEL RECALL**

Date: 6 November 2009

EL (09)A/28Rev 1

Our Ref: MDR 71-10/09

Dear Healthcare Professional,

**Abraxis BioScience Ltd**

**Abraxane 5mg/ml powder for suspension for infusion**

**EU/1/07/428/001**

**Paclitaxel Albumin**

Batch Number	Expiry Date	Pack Size	First Distributed
405693A	12/2009	Single 50 ml vials	12/2008

The batch number quoted in yesterdays drug alert which was checked by the company has now been reported as incorrect. Please ignore the communication sent yesterday and replace it with this document. We apologise for the inconvenience you have experienced.

Abraxis BioScience Ltd are recalling all remaining stock of the above batch as a precautionary measure. Particulate matter has been found in other batches of Abraxane made in the same time period.

Medical Information enquiries should be telephoned to 0207 081 0850.

Please quarantine any remaining stocks of this batch. Recipients will be contacted by Aexxdis (the appointed distributor) and given instructions for stock returns. For any related enquiries, please telephone Aexxdis on 05603 141 956.

Supplies of the licensed UK presentation of Abraxane are not expected to return to normal until the end of Q1 2010.

**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

Date: 6 November 2009

EL (09)A/28Rev 1

Our Ref: MDR 71-10/09

A Dear Healthcare Professional (DHCP) letter is being distributed by Abraxis to physicians which will recommend that patients are switched to alternate therapies if judged clinically acceptable.

For any patients who cannot be switched to other products, imports of unlicensed Abraxane are being permitted. Unlicensed packs will not be labelled in accordance with the normal UK format and the prescriber accepts responsibility for their use in the best clinical interests of the patient.

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 and to General Practitioners and Community Pharmacists for information.

Yours faithfully

Ian Holloway  
MHRA DMRC Manager