

T: 0131-244 2528 F: 0131-244 2375
E: irene.fazakerley@scotland.gsi.gov.uk

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

4 March 2010

Dear Healthcare Professional,
DRUG ALERT NO 5 – CLASS 2

Please find attached drug safety information from the Medicines and Healthcare products Regulatory agency (MHRA) for onward transmission (see list below)

1. Please could all Directors of Pharmacy forward this alert to:-

- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

2. Please could Medical Directors forward this alert to:-

- Relevant Clinics
- Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy Division

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
For distribution to Hospitals, Wholesalers and Relevant Clinics

Date: 4 March 2010

EL (10)A/05

Our Ref: MDR 16-03/10

Dear Healthcare Professional,

Teva UK Ltd

Epirubicin Hydrochloride 2mg/ml
Solution for injection or infusion in vials

PL 00289/1162

Pack Size	Batch Number	Expiry Date	First Distributed
5ml	09D09PB	30 April 2011	May 2009
5ml	09D09PJ	30 April 2011	Dec 2009
25ml	09D20LA	30 April 2011	May 2009
25ml	09G29PA	31 July 2011	Jan 2010

Teva UK Ltd are recalling all remaining stock of the above batches due to errors in both the SPC and PIL. Dilution tables in both documents are **correct** and result in concentrations between 0.6 and 1.6 mg/ml. However, concentrations quoted in the text are wrongly cited as 0.6 to 2.6 mg/ml. The error is present at three locations in the PIL and one in the SPC.

We understand that replacement stock with correct information present will not be available from Teva for about two months. As far as we can establish, suitable alternatives are marketed and should be available from wholesalers.

Contd/.....

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: 4 March 2010

EL (10)A/05

Our Ref: MDR 16-03/10

For medical information enquiries please contact Teva UK Ltd on 0207 540 7117.

Remaining stocks of the above batches should be returned to the original wholesaler for credit. For further stock enquiries please contact Teva UK Customer Liaison Team on 0800 590502.

Recipients of this Drug Alert are requested to bring it to the attention of relevant professionals by copy of this letter. Primary Care Trusts are asked to forward this document to hospitals and relevant clinics.

Yours faithfully

Ian Holloway

DMRC Manager