



Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT
CLASS 2 MEDICINES RECALL

Action within 48 hours

PHARMACY, CLINIC AND WARD LEVEL RECALL

Date: 21 October 2008

EL(08)A/16

Our Ref: MDR 36-10/08

Dear Healthcare Professional,

Pharmacosmos A/S

CosmoFer 50mg/ml solution for infusion and injection **PL 18328/0001**
2 ml and 10ml ampoules containing Iron(III)-as Iron(III)-hydroxide dextran complex

Batch Number	Expiry Date	Pack Size	First Distributed
0546093-4	11/2008	5 X 2ml ampoules	May 2006
0635271-5	8/2009	5 X 2ml ampoules	February 2007
0702746-1	12/2009	5 X 2ml ampoules	March 2007
0710176-1	3/2010	5 X 2ml ampoules	July 2007
0714183-2	3/2010	5 X 2ml ampoules	December 2007
0727853-3	6/2010	5 X 2ml ampoules	January 2008
0734209-1	8/2010	2 X 10ml ampoules	March 2008
0734209-4	8/2010	2 X 10ml ampoules	September 2008
0749461-2	11/2010	5 X 2ml ampoules	June 2008

Pharmacosmos A/S are recalling all remaining stock of the above batches due to a potential risk of formation of precipitate in the solution.

We understand this product is mainly used in hospitals but some product is supplied via Community Pharmacies.

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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All unused stock of the above batches should be quarantined and returned for credit via the original supplier. For returns and credit enquiries, please contact the UK distributor Vitaline Ltd on 01844 269007

Medical information can be obtained from the UK distributor, Vitaline Ltd on 01844 269007.

Recipients of this Drug Alert should bring this to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to bring this to the attention of relevant clinics, General Practitioners and Community Pharmacists by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager