

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 17, 18, 19, 20 and 21 – 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 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
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Telephone: +44 (0)20 7084 2574

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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALE LEVEL RECALL

Date: 01 July 2009

EL (09)A/17

Our Ref: MDR 58-06/09

Dear Healthcare Professional,

Milpharm Limited

Product distributed in Karib Kemi Pharm Limited livery ONLY

Fluoxetine 20mg Capsules

PL 16363/0064

Pack size: 30 Capsules

Milpharm Limited are recalling all unexpired stock of the above product **in Karib Kemi Pharm Limited livery only (batches beginning with 'T')** due to serious Good Manufacturing Practice (GMP) deficiencies found during an inspection of their contract manufacturer. **Please note stock with the same PL number but in different liveries is not affected by this recall.**

All unused, unexpired stock of the above batches should be quarantined and returned for credit.

For any Medical Information enquiries related to this case please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891

For enquiries related to stock returns and credit please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891

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

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

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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALER LEVEL RECALL

Date: 01 July 2009

EL (09)A/18

Our Ref: MDR 58-06/09

Dear Healthcare Professional,

Karib Kemi Pharm Limited

Multiple Product Drug Alert

Doxazosin 2mg and 4mg Tablets; Fluoxetine 20mg Capsules

Doxazosin 2mg Tablets

PL 18224/0029

(Doxazosin mesilate)

Product in Karib Kemi Pharm Limited livery

Batch Number	Expiry Date	Pack Size	First Distributed
T1D 011007	09/2009	28	29/01/2008
T1D 010408	03/2010	28	16/05/2008
T1D 021108	10/2010	28	09/01/2009
T1D 010509	04/2011	28	29/02/2009
T1D 020509	04/2011	28	29/02/2009

Product in Consilient Health Limited livery

Batch Number	Expiry Date	Pack Size	First Distributed
T1D 010108	12/2009	28	07/03/2008
T1D 011108	10/2010	28	09/01/2009

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Date: 01 July 2009

EL (09) A/18

MDR 58-06/09

Doxazosin 4mg Tablets
(Doxazosin mesilate)

PL 18224/0030

Product in Karib Kemi Pharm Limited livery

Batch number	Expiry Date	Pack Size	First Distributed
T2D 010707	06/2009	28	20/12/2007
T2D 020707	06/2009	28	20/12/2007
T2D 010807	07/2009	28	07/04/2008
T2D 020807	07/2009	28	14/07/2008
T2D 010108	12/2009	28	14/07/2008
T2D 010208	01/2010	28	03/11/2008
T2D 010408	03/2010	28	21/10/2008
T2D 020408	03/2010	28	21/10/2008
T2D 040408	03/2010	28	17/11/2008
T2D 011108	10/2010	28	09/01/2009
T2D 010409	03/2011	28	26/05/2009
T2D 010509	04/2011	28	26/05/2009
T2D 020509	04/2011	28	29/02/2009
T2D 030509	04/2011	28	27/05/2009
T2D 040509	04/2011	28	27/05/2009
T2D 050509	04/2011	28	27/05/2009

Product in Consilient Health Limited livery

Batch number	Expiry Date	Pack Size	First Distributed
T2D 020108	12/2009	28	04/11/2008

Date: 01 July 2009

EL (09)A/18

MDR 58-06/09

Fluoxetine 20mg Capsules
(Fluoxetine Hydrochloride)**PL 18224/0059****Product in Karib Kemi Pharm Limited livery**

Batch number	Expiry Date	Pack Size	First Distributed
TF8 011208	11/2011	30	13/03/2009
TF8 021208	11/2011	30	01/04/2009
TF8 031208	11/2011	30	01/04/2009
TF8 041208	11/2011	30	01/04/2009
TF8 051208	11/2011	30	01/04/2009
TF8 010109	12/2011	30	27/05/2009
TF8 020109	12/2011	30	27/05/2009
TF8 030109	12/2011	30	27/05/2009
TF8 010209	01/2012	30	27/05/2009
TF8 020209	01/2012	30	27/05/2009
TF8 030209	01/2012	30	27/05/2009
TF8 040209	01/2012	30	08/06/2009

Karib Kemi Pharm Limited are recalling the above products due to serious Good Manufacturing Practice (GMP) deficiencies found during an inspection of their contract manufacturer.

All unused stock of the above batches should be quarantined and returned for credit.

For any Medical Information enquiries related to this case please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891.

Date: 01 July 2009

EL (09)A/18

MDR 58-06/09

For enquiries related to stock returns and credit for products in Karib Kemi Pharm Limited livery please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891.

For enquiries related to stock returns for products in Consilient Health Limited livery please call 0208 9562697

For enquiries related to credit for products in Consilient Health Limited livery please call 00353 1 2057753

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

Yours faithfully

Alison Bunce
Pharmaceutical Assessor, DMRC



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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALER LEVEL RECALL

Date: 01 July 2009

EL (09)A/19

Our Ref: MDR 58-06/09

Dear Healthcare Professional,

LPC Medical (UK) Limited

Multiple Product Drug Alert

Products in Karib Kemi Pharm livery ONLY

Product	Pack Sizes	PL Number
Co-Amilozide 5/50 Tablets	28	19348/0015
Metformin 500mg Tablets	28 and 84	19348/0013
Metformin 850mg Tablets	56	19348/0014
Naproxen 250mg Tablets	28	19348/0008
Naproxen 500mg Tablets	28	19348/0009

LPC Medical (UK) Limited are recalling all unexpired stock of the above products **in Karib Kemi Pharm livery only** due to serious Good Manufacturing Practice (GMP) deficiencies found during an inspection of their contract manufacturer.

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01 July 2009

EL (09)A/19

MDR 58-06/09

All unused unexpired stock of these products should be quarantined and returned for credit.

For any medical Information enquiries related to this case please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891

For enquiries related to stock returns and credit please call Karib Kemi Pharm Limited on 07732 166641 or 07732 166891

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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALE LEVEL RECALL

Date: 01 July 2009

EL (09)A/20

Our Ref: MDR 59-06/09

Dear Healthcare Professional,

Sandoz Limited

Multiple Product Drug Alert

Product	Pack Size	PL Number
Baclofen 10mg Tablets	84	04416/0160
Fluoxetine 20mg Capsules	30	04416/0330
Metformin 500mg Tablets	28	04416/0300
Metformin 850mg Tablets	56	04416/0301

Sandoz Limited are recalling the above products due to serious Good Manufacturing Practice (GMP) deficiencies found during an inspection of one of their contract manufacturers.

All unexpired stock of these products should be quarantined and returned for credit.

For any Medical Information enquiries related to this case please call Sandoz Limited Medical Information on 01420 478301.

For enquiries related to stock returns and credit please call Sandoz Limited Customer Service on 01420 478301 or email sales.sandoz-gb@sandoz.com

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

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Date: 01 July 2009

EL (09)A/20

MDR 59-06/09

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Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC



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CLASS 2 MEDICINES RECALL

Action Within 48 Hours

PHARMACY AND WHOLESALE LEVEL RECALL

Date: 01 July 2009

EL (09)A/21

Our Ref: MDR 78-06/09

Dear Healthcare Professional,

Strandhaven Limited

Amlodipine 5mg and 10mg Tablets

PL 15764/0015 &

PL 15764/0016

(Amlodipine besilate)

5mg Tablets			
Batch Number	Expiry Date	Pack Size	First Distributed
T7A030806	07/2009	28	24/08/2007
T7A011007	09/2010	28	09/01/2008
T7A021007	09/2010	28	17/01/2008
T7A031007	09/2010	28	08/10/2009
T7A041007	09/2010	28	29/10/2008

10mg Tablets			
Batch Number	Expiry Date	Pack Size	First Distributed
T8A030806	07/2009	28	24/08/2007
T8A011007	09/2010	28	09/01/2008
T8A021007	09/2010	28	21/12/2007
T8A031007	09/2010	28	14/10/2008
T8A041007	09/2010	28	19/11/2008

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Date: 01 July 2009

EL (09)A/21

MDR 78-06/09

Strandhaven Limited are recalling the above products due to serious Good Manufacturing Practice (GMP) deficiencies found during an inspection of their contract manufacturer.

All unused stock of the above batches should be quarantined and returned for credit.

For Medical Information enquiries related to this case please call Strandhaven Limited on 0208 5909399

For enquiries related to stock returns and credit please call Strandhaven Limited on 0208 5909399

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

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC