Healthcare Quality and Strategy Directorate Pharmacy and Medicines Division

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IMMEDIATE MESSAGE TO:

- 1. Directors of Pharmacy
- 2. Medical Directors NHS Boards
- 1 February 2017





Dear Healthcare Professional,

DRUG ALERT CLASS 3 no 3 2017 – Action within 5 days

Please see the attached drug alert for onward transmission as below. Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors forward this alert to:-

- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY Pharmacy and Medicines Division







DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days Pharmacy, Wholesaler and Retailer Level Recall

Date: 01 February 2017

EL (17)A/03

Our Ref: MDR 96-01/17

Dear Healthcare Professional,

Bayer plc

Alka-Seltzer Original PL 00010/0511

Alka-Seltzer XS

PL 00010/0510

Product	Batch Number	Expiry Date	Pack Size	First Distributed
Alka-Seltzer Original	BTAH310	31 Mar 2019	1 x 10	20 Jul 2016
Alka-Seltzer Original	BTAH311	31 Mar 2019	1 x 10	12 Aug 2016
Alka-Seltzer Original	BTAH320	28 Feb 2019	1 x 20	22 Jun 2016
Alka-Seltzer Original	BTAHBE0	31 May 2019	1 x 20	09 Jun 2016
Alka-Seltzer Original	BTAHLE0	30 Apr 2019	1 x 10	14 Jun 2016
Alka-Seltzer XS	BTAHE33	30 Nov 2018	1 x 20	27 Jul 2016
Alka-Seltzer XS	BTAHE35	30 Nov 2018	1 x 20	27 Jul 2016
Alka-Seltzer XS	BTAHNX2	28 Feb 2019	1 x 20	02 Sep 2016
Alka-Seltzer XS	BTAHW52	31 Mar 2019	1 x 20	07 Nov 2016
Alka-Seltzer XS	BTAHE32	30 Nov 2018	1 x 20	16 Jun 2016
Alka-Seltzer XS	BTAHE34	30 Nov 2018	1 x 20	19 Jun 2016
Alka-Seltzer XS	BTAHHNX1	28 Feb 2019	1 x 20	10 Aug 2016
Alka-Seltzer XS	BTAHNX3	28 Feb 2019	1 x 20	28 Sep 2016

Bayer plc is voluntarily recalling the above batches due to an issue with the blister foil. A problem with the blistering process has resulted in the potential for small holes or cracks being present in the aluminium layer of the tablet blister material, which are not visible to the consumer. This could result in compromise of the moisture barrier provided by the aluminium layer. Bayer has assessed this defect as unlikely to pose a safety risk for consumers, therefore affected batches are not being recalled to patient level.

All remaining units of the affected batches should immediately be quarantined. Bayer is contacting potentially affected customers by letter and will arrange uplift of affected stock following receipt of a form listing affected stock in hand. A copy of the form is attached for any customers who may not receive a letter from Bayer.





Date: 01 February 2017

EL (17) A/03

MDR 96-01/17

For stock enquiries, please contact Bayer plc by telephone on 01635 563920 or by email to orders-uk@bayer.com

For medical enquiries please contact Bayer plc by telephone on 01635 563232 or by email to <u>consumerhealthuk@bayer.com</u>

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional Teams are asked to forward this to community pharmacists for action. **NB It is not necessary to forward this notice to GPs.**

Yours faithfully

Alison Bunce

Pharmaceutical Assessor Defective Medicines Report Centre 151 Buckingham Palace Road London SW1W 9SZ Telephone +44 (0)20 3080 6574

Alka Seltzer Bayer Batch Recall Confirmation of Quarantined Batches

Please complete the following information and forward to Bayer Customer Services by Email: orders-uk@bayer.com or Fax: 01635 563429



Material Description	Batch/Lot Number	Expiry Date	Quantity of consumer unit in Stock	Quantity Quarantined	Replacement stock required Yes/No
ALKA ORIGINAL 10'S	BTAH310	31/03/2019			
ALKA ORIGINAL 10'S	BTAH311	31/03/2019			
ALKA ORIGINAL 20'S	BTAH320	28/02/2019			
ALKA ORIGINAL 20'S	BTAHBE0	31/05/2019			
ALKA ORIGINAL 10'S	BTAHLE0	30/04/2019			
ALKA XS 20'S	BTAHE33	30/11/2018			
ALKA XS 20'S	BTAHE35	30/11/2018			
ALKA XS 20'S	BTAHNX2	28/02/2019			
ALKA XS 20'S	BTAHW52	31/03/2019			
ALKA XS 20'S	BTAHE32	30/11/2018			
ALKA XS 20'S	BTAHE34	30/11/2018			
ALKA XS 20'S	BTAHNX1	28/02/2019			
ALKA XS 20'S	BTAHNX3	28/02/2019			

Wholesaler/Pharmacy/Retailer		
Form Completed By:	Position:	
Email address:	Telephone No.:	
Signature:	Date:	