T: 0131-244 2528 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

18 December 2014

Dear Healthcare Professional,

## DRUG ALERT CLASS 2 no 19 2014 - Action within 48 hours

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
- Chief Pharmacists to forward on to Medicines Information Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

# IRENE FAZAKERLEY

Finance,e-Health and Pharmaceuticals Directorate









# DRUG ALERT

**CLASS 2 MEDICINES RECALL** 

Action Within 48 Hours Pharmacy Level Recall

Date: 18 December 2014

EL (14)A/19

Our Ref: MDR 27-12/14

Dear Healthcare Professional,

#### Lundbeck Limited

# Ebixa 5mg/pump actuation 50ml bottle Ebixa 5mg/pump actuation 100ml bottle

#### EU/1/02/219/005 EU/1/02/219/006

#### (Memantine hydrochloride)

Lundbeck Limited is recalling specific batches of Ebixa 5mg/pump actuation 50ml and 100ml bottles, please see batch details in the Appendix. This is because of a fault with some of the pump devices which may result in suboptimal dosage of the product. We understand that no immediate or major hazard for the patient is expected however it cannot be excluded that individual patients may potentially experience worsening of their condition from under-dosage.

All remaining stock of the affected batches should be quarantined and returned to Alliance Healthcare Limited for credit. The only unaffected stock currently available is the 50ml bottle but Lundbeck Limited is working closely with its suppliers to bring stocks of 100ml bottles to the market as quickly as possible.

For enquiries relating to stock return, please call your local Alliance Healthcare Limited Local Service Centre Customer Services Team.

For medical information enquiries, please contact Lundbeck Medical Information, tel 01908 638972; email <u>ukinfo@lundbeck.com</u>; fax 01908 638935.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

Alison Bunce

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

Medicines and Healthcare Products Regulatory Agency



EL (14)A/19

Our Ref: MDR 27-12/14

# APPENDIX: Batches of Ebixa 5mg/pump actuation being recalled

Ebixa 5 mg/pump actuation			
50 ml bottle	Batch number	Expiry date	First distributed
	363530	12.2016	17 Jun 2013
	363729	12.2016	19 Jun 2013
	364381	01.2017	09 Aug 2013
	364620	02.2017	19 Aug 2013
	364639	02.2017	23 Sep 2013
	365766	07.2017	29 Oct-2013
	366902	07.2017	22 Nov 2013
	369095	09.2017	13 Jan 2014
	370325	10.2017	15 May 201
	471986	12.2017	24 Jul 2014
	473236	03.2018	14 Sep 2014
	474349	04.2018	03 Nov 2014
Ebixa 5 mg/pump actuation			
100 ml bottle	Batch number	Expiry date	First distributed
	364384	02.2017	06 Aug 2013
	365579	04.2017	02 Sep 2013
	366903	05.2017	31 Oct 2013
	369090	09.2017	02 Jan 2014
	370328	11.2017	07 Feb 2014
	471112	01.2018	20 Mar 2014
	471266	01.2018	02 May 2014
	473233	02.2018	14 Jul 2014
	474348	03.2018	25 Aug-2014
	476354	04.2018	06 Nov 2014