

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Health Policy
Date:	3 January 2018
Reference:	CEM/CPhA/2018/1
Category:	Class 2: Action within 48 Hours)
Title:	Drug Alert Class 2 - Action Within 48 Hours, Winthrop Pharmaceuticals Uk Limited Trading As Zentiva, Molipaxin 100mg Capsules.
What is this about:	 Full details are set out below.
Why has it been sent:	For your information and to pass on to Colleagues

Issue:

Precautionary recall of one batch due to the possibility of metal particles within units from the batch because a metal detector may not have been functioning during manufacture. Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

cc: Public Health Wales

Consultants in Pharmaceutical Public Health

Chief Executives, NHS Trusts

Principal Pharmacist Welsh Quality Control

Principal Pharmacist Continuing Care Services

Principal Pharmacist Welsh Medicines Information Centre

CSSIW

NHS Direct



Medicines & Healthcare products
Regulatory Agency



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Pharmacy, Hospital, Mental Health Trust and Wholesaler Level Recall

Date: 03/01/2018

EL (18) A/01

Our Ref: MDR 061-12/17

Dear Healthcare Professional,

Winthrop Pharmaceuticals UK Limited Trading as Zentiva

Mollipaxin 100 mg capsules
(Trazodone hydrochloride)

PL 17780/0618

Batch Number	Expiry Date	Pack Size	First Distributed
3650817	07/ 2020	56 Capsules	16/10/2017

Brief description of the problem

A precautionary recall is being carried out due to the potential that during manufacture of the batch, the metal detector may not have functioned and therefore that the presence of metal particles would not have been detected, if they were present. Although there is no evidence of metal particles within units from the batch, the batch is being recalled as a precautionary measure.

Please return affected stock from this batch to your supplier.

Contact for stock information – GB-CustomerServices@sanofi.com

Contact for medical information - uk-medicalinformation@sanofi.com

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 relevant clinics, hospitals, mental health trusts, general practitioners and community pharmacists for information.

Yours faithfully

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