



T: 0131-244-2528  
E: irene.fazakerley@gov.scot

**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

25 October 2019

Dear Healthcare Professional,

**DRUG ALERT CLASS 2 MEDICINES RECALLS NO 29 AND 30 2019 ACTION WITHIN 48 HOURS ROSEMONT PHARMACEUTICALS AND OMEGA PHARMA LTD TRADING AS PERRIGO RANITIDINE 150MG/10ML ORAL SOLUTION, ZANTAC 75 RELIEF TABLETS AND TABLETS**

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:-

- 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**  
**Medicines Policy Team**





# DRUG ALERT

## CLASS 2 MEDICINES RECALL

**Action Within 48 Hours**  
**Pharmacy/Wholesaler Level Recall**

Date: 25 October 2019

EL (19)A/29

Our Ref: MDR 56-09/19

Dear Healthcare Professional,

### **Rosemont Pharmaceuticals Limited (part of the Perrigo group)**

Product	PL Number
Ranitidine 150mg/10ml Oral Solution	00427/0132

Rosemont Pharmaceuticals Limited is recalling all unexpired stock of the above products from pharmacies as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

#### **Advice for healthcare professionals**

- Stop supplying the above products immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.

This is an on-going issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.



## **Company contacts for further information**

For stock control enquiries please contact Perrigo Customer Service team on  
+44 (0)1226 704711 or [customerservice@perrigouk.com](mailto:customerservice@perrigouk.com)

For medical information enquiries please contact Perrigo Pharmacovigilance Department on  
+44 (0)203 598 9603 or [UKLOCustomerService@perrigo.com](mailto:UKLOCustomerService@perrigo.com)

Recipients 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, general practitioners and community pharmacists.

Yours faithfully

**Defective Medicines Report Centre  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
Telephone +44 (0)20 3080 6574**



## DRUG ALERT

### CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy/Wholesaler/Retail Store Level Recall

Date: 25 October 2019

EL (19)A/30

Our Ref: MDR 56-09/19

Dear Healthcare Professional,

### Omega Pharma Limited trading as Perrigo

Product	PL Number
Zantac 75 Relief Tablets	02855/0081
Zantac 75 Tablets	02855/0082

### Galpharm International Limited (part of the Perrigo Group)

Product (GSL)	PL Number
Galpharm Indigestion Relief 75mg Tablets	16028/0122
Boots Heartburn & Indigestion Relief 75mg Tablets	16028/0122
Kirkland Indigestion Relief 75mg Tablets	16028/0122
Morrisons Indigestion & Heartburn Relief 75mg Tablets	16028/0122

Product (P)	PL Number
Boots Heartburn & Indigestion Relief 75mg Tablets	16028/0123

Generic Name: Ranitidine

Omega Pharma Limited and Galpharm International Limited are recalling all unexpired stock of the above products from pharmacies and retail stores as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.



### **Advice for healthcare professionals and retail stores**

- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them to contact their GP, pharmacist or healthcare professional to review ongoing treatment.

This is an on-going issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.

### **Company contacts for further information**

For stock control enquiries please contact Perrigo Customer Service team on +44 (0)1226 704711 or [customerservice@perrigouk.com](mailto:customerservice@perrigouk.com)

For medical information enquiries please contact Perrigo Pharmacovigilance Department on +44 (0)203 598 9603 or [UKLOCustomerService@perrigo.com](mailto:UKLOCustomerService@perrigo.com)

### **Omega Pharma Ltd (Zantac Products):**

Please contact the Alloga UK Credits team via telephone on 01773 515172 or via email [AllogaUK.Credit.Claims@Alloga.co.uk](mailto:AllogaUK.Credit.Claims@Alloga.co.uk) to arrange collection of any stock subject to this recall.

Recipients 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, general practitioners and community pharmacists.

Yours faithfully

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**10 South Colonnade**  
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**London**  
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