

Safeguarding public health  
Defective Medicines Report Centre  
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MHRA

## DRUG ALERT

### CLASS 3 MEDICINES RECALL

Action Within 5 Days  
PHARMACY LEVEL RECALL

Date: 26 February 2013

EL (13)A/04 Rev 1

Our Ref: MDR 46-12/12

Dear Healthcare Professional,

**ratiopharm GmbH**

**Desloratadine ratiopharm 5mg film-coated tablets (Teva livery) EU/1/11/746/006**

Batch Number	Expiry Date	Pack Size	First Distributed
009263	30 Sep 2014	1 x 30	15 Feb 2012
009264	30 Sep 2014	1 x 30	15 Feb 2012
010168	31 Mar 2015	1 x 30	14 Jun 2012
010321	31 Mar 2015	1 x 30	12 Jun 2012

**Please replace the Drug Alert issued on 13 February 2013 with this revised document. Teva UK Limited has informed us that the batch numbers were expressed incorrectly on the original Alert. The table, above, has now been corrected. The company apologises for any additional inconvenience this may cause.**

Teva UK Limited is recalling all remaining stock of the above batches because higher than expected levels of impurities were detected during routine stability testing. Although there are currently no concerns relating to patient safety, it is possible that impurities may exceed specification towards the end of the shelf-life.

Remaining stocks of these batches should be quarantined and returned to the original supplier for credit. For further stock enquiries please contact Teva UK Customer Liaison Team on 0800 590502.

For medical information enquiries please contact Teva UK limited by phone on 0207 5407117 or by email to [medinfo@tevauk.com](mailto:medinfo@tevauk.com).

**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 (MHRA)  
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An executive agency of the Department of Health



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 and to General Practitioners and Community Pharmacists for information.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC