

Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Clinic and Wholesaler Level Recall

Date: 27 February 2013

EL (13)A/07

Our Ref: MDR 56-02/13

Dear Healthcare Professional,

Sanofi-aventis

Brochlor 1% w/w Eye Ointment
(Chloramphenicol)

PL 04425/0367

Batch Number	Expiry Date	Pack Size	First Distributed
122702	31/12/2016	1 x 4g	01/02/2013
122727	31/12/2016	1 x 4g	12/02/2013

Sanofi-aventis are recalling all remaining stock of these batches to Pharmacy, clinic and wholesaler level, due to an issue with seal integrity and compromised sterility assurance, introduced during the filling process.

Remaining stocks of the affected batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock returns please contact Sanofi-aventis Customer Services on 0800 854430 or email GB-CustomerServices@sanofi.com.

For medical information enquiries please contact Sanofi-aventis Medical Information on 0845 3727101 or email uk-medicalinformation@sanofi.com.

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, General Practitioners, Optometrists and Community Pharmacists for information.

Contd/...

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)
151 Buckingham Palace Road London SW1W 9SZ UK
T 020 3080 6000 www.mhra.gov.uk

An executive agency of the Department of Health



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Yours faithfully
Adam Burgess
MHRA DMRC Manager