

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

Dear Healthcare Professional,

**DRUG ALERT NO 31 – CLASS 2**

Please find attached revised drug safety information from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Directors of Pharmacy forward this alert to:-
  - Community Pharmacists
  - Hospital pharmacists
  - Chief Pharmacists to forward on to Medicines Information Pharmacists
2. Please could Medical Directors forward the message on to :-
  - General Practitioners
  - Dispensing Doctors
  - Relevant Clinics
  - Chief Executives NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY  
Pharmacy Division

\* NB: Drug alerts have the following classifications:

1. Action now (including out-of-hours);
2. Action within 48 hours;
3. Action within 5 days;
4. Caution in use



**Safeguarding public health**

**Defective Medicines Report Centre  
Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ  
Telephone: +44 (0)20 7084 2574**

**Fax: +44 (0)20 7084 2676**

**DRUG ALERT**

**CLASS 2 MEDICINES RECALL**

**Action Within 48 Hours  
PHARMACY OR EQUIVALENT LEVEL RECALL**

Date: 20 November 2009

EL (09)A/31

Our Ref: MDR 35-11/09

Dear Healthcare Professional,

**Procter & Gamble (Health & Beauty Care) Ltd**

**Vicks Sinex Micromist**

**PL 00129/0133**

**(Oxymetazoline Hydrochloride 0.05% w/v aqueous  
nasal spray solution)**

Batch Number	Expiry Date	Pack Size	First Distributed
9224028832	12/08/2013	15ml Nasal Spray	26 August 2009

Procter & Gamble (Health & Beauty Care) Ltd are recalling the above batch due to the detection during routine testing of microbial contamination in a small amount of product from another batch in the USA which was derived from the same bulk batch (ie pre-packed product). The company's analysis to date shows this problem is limited to a single batch of bulk involving three packed batches, only one of which is a UK batch.

No microbial contamination has been detected in UK packs from batch 9224028832, but the marketing authorisation holder wishes to recall this batch as a precautionary measure whilst testing is ongoing and the causes are being investigated.

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**  
Market Towers 1 Nine Elms Lane London SW8 5NQ  
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

**An executive agency of the Department of Health**

Date: 20 November 2009

EL (09)A/31

MDR 35-11/09

We understand that the bacteria identified in the USA samples are *Burkholderia cepacia*. There have been no reports of illness. However, the bacteria could cause serious infections for individuals with a compromised immune system, or those with chronic lung conditions, such as cystic fibrosis. *Burkholderia cepacia* poses little medical risk to healthy individuals.

For Medical Information enquiries, please call Procter & Gamble on 0800 555515

For queries relating to stock return please contact your Wholesaler/Head Office. If further information is required, please contact Procter & Gamble on 0800 555515

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