Safeguarding public health

Press Release

Date: Wednesday 2 November 2011
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Mouthwash recalled due to bacterial contamination

Colgate Periogard 0.2% chlorhexidine mouthwash is being recalled by Colgate-Palmolive today as a precaution due to potential bacterial contamination.

The bacteria concerned, Burkholderia, are unlikely to cause harm to healthy people but may cause infection in those with a compromised immune system or with chronic lung conditions such as cystic fibrosis.

Medicines and Healthcare products Regulatory Agency (MHRA) Director of Inspection, Enforcement and Standards, Gerald Heddell said: “For healthy people there should be no problems, however, for some there could be a small potential risk of infection.

“If people do have any suspected side effects then they should contact their GP.”

Colgate-Palmolive initiated the recall in 11 different countries within Europe and Australasia following a quality defect.

Microbiological testing of retained samples from the affected batches confirmed bacterial contamination.

The manufacturer’s decision to recall the affected batches was taken to reduce as much as possible any risk to consumers while a full investigation is undertaken.

There have been no reports of adverse reactions or illnesses associated with this issue and Colgate-Palmolive is working closely with the MHRA to take any further measures if necessary.

Consumers are asked to contact Colgate-Palmolive (UK) Ltd on their freephone helpline 00800 3213 2132 for details on how to return the product.

Ends

Notes to Editor

1. Periogard 0.2% Oromucosal Solution (300ml) is a chlorhexidine mouth rinse and is a General Sales Licence medicine, which means they are available in retail outlets and do not need to be sold under the supervision of a pharmacist.

2. Affected batches (all UK stock) are:

Batch Number	Expiry Date	Pack Size	First Distributed
9196CHG11B	Jan 2012	300ml	Aug 2009
9197CHG11B	Jan 2012	300ml	Sep 2009
9198CHG11B	Jan 2012	300ml	Aug 2009
0103CHG12B	Oct 2012	300ml	Apr 2010
0103CHG11B	Oct 2012	300ml	May 2010
0104CHG11B	Oct 2012	300ml	Apr 2010
0155CHG11B	Dec 2012	300ml	Jul 2010
0158CHG11B	Dec 2012	300ml	Jul 2010
0158CHG12B	Dec 2012	300ml	Jul 2010
0250CHG11B	Jan 2013	300ml	Sep 2010
1068CHG11B	Aug 2013	300ml	Mar 2011
1069CHG11B	Aug 2013	300ml	Mar 2011
1236CHG11B	Jan 2014	300ml	Oct 2011
1237CHG11B	Jan 2014	300ml	Oct 2011

3. MHRA link to the Drug Alert issued Wednesday 2 November 2011.
http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON134742

4. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk