

Press Release

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Product recall of saline nasal spray due to bacterial contamination

The Medicines and Healthcare products Regulatory Agency (MHRA) has received warning of possible bacterial contamination in batches of the saline nasal spray Sterimar Isotonic 100ml. The spray is sold online and at high street retailers and is commonly used to cleanse the nasal passage.

As part of its regulatory requirement the manufacturer has informed the MHRA of a bacterial infection in two batches of the spray. The two bacteria identified are commonly found in soil, water and hospital environments and human infections are rare. The bacteria shouldn't affect healthy people. However, those who suffer from existing sinus or nasal problems, have recently undergone surgery or have a weakened immune system may be at risk. The possible symptoms exhibited can be nasal or facial tenderness, discoloured mucus or a fever.

Consumers are asked that if they have any of the affected batches, to stop using the product immediately and return it to the retailer. If they exhibit any of the symptoms listed above then they should consult a healthcare professional.

The affected batches are **FE1248b** and **FE1249**. The batch number can be located on the product packaging and on the base of the can.

Ends

Notes to Editor

1. See link to the Field Safety Notice below:

<http://www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con140681.pdf>

2. The manufacturer has accounted for all stock in the two affected batches of Sterimar Isotonic 100 ml apart from 2,452 individual cans.

3. The two types of bacteria found in some of the affected batches are *Pseudomonas stutzeri* and *Sphingomonas paucimobilis*. It has an extremely limited role as an infectious agent and human infections are rare. Most infections are associated with immunocompromised individuals. The infections can be treated with antibiotics.

4. If you have any further questions on the product or affected batches please contact the manufacturer Church & Dwight UK Ltd on 0800 055 6993.

5. 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