

Medical Device Alert

Action

Ref: MDA/2011/033 Issued: 07 April 2011 at 15:30

Device

Optilube lubricating jelly supplied as 150 x 5g sachets per box.

Lot 25092010.

NHS Supply Chain code EXC027.

Manufactured by Optimum Medical Solutions.



Problem	Action
Part of the specified lot number was found to be non-sterile and contaminated with the yeast <i>Candida guilliermondi</i> , which can cause infection in patients that may be immunocompromised and those with malignancy.	<ul style="list-style-type: none"> Do not use sachets from this lot number. Quarantine and return all unused sachets and boxes to Optimum Medical Solutions.
Action by	
All those who supply or use lubricating jelly for general purpose use.	
CAS deadlines	Contact
Action underway: 14 April 2011 Action complete: 21 April 2011	Manufacturer Optimum Medical Solutions Tel: 08456 435 479 Fax: 01142 383 826 Email: enquiries@optimummedical.co.uk

Problem

Affected product was distributed between 10 November 2010 and 31 January 2011.

Optimum Medical Solutions issued a Field Safety Notice dated 08 February 2011 recalling all product from this lot. Click [here](#) to go to a list containing this Field Safety Notice.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All clinical staff
- All theatres
- All wards
- Health and safety managers
- Medical directors
- Nursing directors
- Risk managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Community midwives
- Community nurses
- District nurses
- General practitioners
- Health visitors
- Minor injury units
- NHS walk-in centres
- Palliative care teams
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Customer Services Department
Optimum Medical Solutions
47 Park Square East
Leeds
LS1 2NL

Tel: 08456 435 479

Fax: 01142 383 826

Email: enquiries@optimummedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/033** or **2011/002/002/401/007**

Technical aspects

Ian Smith
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7306
Fax: 020 8754 3965
Email: ian.smith@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7126
Fax: 020 8754 3965
Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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