

Medical Device Alert

Action

Ref: MDA/2010/067 Issued: 26 August 2010 at 11:30

Device

Contact lens solution.

AMO Complete® multi-purpose solution.

Manufactured by Abbott Medical Optics Inc (AMO).



Problem	Action
<p>Recall of specific product lot numbers.</p> <p>Sterility of the product may be compromised due to poor fitting caps.</p>	<ul style="list-style-type: none"> Do not supply or use affected lots of AMO Complete multi-purpose contact lens solution as identified in the manufacturer's Field Safety Notice. Return all affected product to the manufacturer. Report adverse incidents to the manufacturer and the MHRA.
Action by	
<p>Ophthalmologists, pharmacists, opticians and optometrists who:</p> <ul style="list-style-type: none"> supply contact lens solutions manage individuals who wear contact lenses. 	
CAS deadlines	Contact
<p>Action underway: 02 September 2010</p> <p>Action complete: 23 September 2010</p>	<p>Manufacturer Dr Michael Faust Abbott Medical Optics Tel: +49 7243 729 474 Fax: +49 7243 58971 474 Email: michael.faust@amo.abbott.com</p>

Device

Complete [®] multi-purpose solution – affected lots in the UK			
Product code	Bottle size	Lot number	Expiration date
93505	360 ml	AH01072	April 2012
93515	240 ml	AH01225	April 2012

Problem

The manufacturer, Abbott Medical Optics Inc (AMO), has identified that due to a manufacturing error certain lots of product may have poor fitting caps, which could compromise the sterility of the product.

Product that is non-sterile could have the potential to cause eye infections.

The manufacturer has issued a [Field Safety Notice](#) recalling affected product.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- A&E departments
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Private medical practitioners

Primary care trusts to:

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

- Community optometrists
- Community pharmacists
- Directors of public health
- Dispensing opticians

Contact

Manufacturer

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/0067** or **2010/007/023/081/008**

Technical aspects

Ian Smith or Michelle Kelly
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3306/3145
Fax: 020 7084 3145
Email: ian.smith@mhra.gsi.gov.uk
michelle.kelly@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
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London SW8 5NQ
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Fax: 020 7084 3111
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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