

# Medical Device Alert

## Action

Ref: MDA/2010/077 Issued: 4 October 2010 at 14:00

### Device

Contact lenses.

Softperm (synergicon A) daily wear.

Manufactured by Ciba Vision Corporation.



Problem	Action
<p>Recall of specific product.</p> <p>Product may cause eye infections and/or burning and stinging upon initial insertion of the lens.</p>	<ul style="list-style-type: none"> <li>Do not supply Softperm contact lenses as identified in the manufacturer's <a href="#">Field Safety Notice</a>.</li> <li>Return all unused product to Ciba Vision (UK) Limited.</li> <li>Consider contacting end users who have received affected product requesting that they return unused product to their eye care professional.</li> <li>Report adverse incidents to the manufacturer and the MHRA.</li> </ul>
<h3>Action by</h3> <p>Ophthalmologists, opticians and optometrists who:</p> <ul style="list-style-type: none"> <li>supply contact lenses</li> <li>manage individuals who wear contact lenses.</li> </ul>	
CAS deadlines	Contact
<p>Action underway: 11 October 2010</p> <p>Action complete: 04 November 2010</p>	<p><b>UK Distributor:</b>            Ciba Vision (UK) Limited            Tel: 01489 785 580            Fax: 01489 786 802            Email: <a href="mailto:regulatory.enquiries@cibavision.com">regulatory.enquiries@cibavision.com</a></p>

## Device

All lots supplied after March 13 2009.

## Problem

Following a change to the vial stopper of the packaging, Ciba Vision Corporation identified that:

- Sterility of the product may be compromised. Product that is non-sterile can cause eye infections.
- The pH of the storage solution may be out of specification, which can cause burning and stinging upon initial insertion of the lens.

The manufacturer issued a [Field Safety Notice](#) informing eye care professionals that they can return unused product.

The product is no longer manufactured by Ciba Vision Corporation.

## Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- 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
- Optometrists

#### Establishments registered with the 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
- Directors of public health
- Dispensing opticians

## Contacts

Ciba Vision (UK) Limited  
Flanders Road, Hedge End  
Southampton, Hampshire  
SO30 2LG

Tel: 01489 785 580

Fax: 01489 786 802

Email: [regulatory.enquiries@cibavision.com](mailto:regulatory.enquiries@cibavision.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/077** or **2010/006/008/081/004**.

Please note that telephone numbers for the MHRA contacts below will change on 25 October 2010. From that date please contact the MHRA Central Enquiry Point on 020 7084 2000 and ask for the person by name.

### Technical aspects

Ian Smith or Michelle Kelly  
Medicines & Healthcare products Regulatory Agency  
Tel: 020 7084 3306/3145  
Email: [ian.smith@mhra.gsi.gov.uk](mailto:ian.smith@mhra.gsi.gov.uk)  
[michelle.kelly@mhra.gsi.gov.uk](mailto:michelle.kelly@mhra.gsi.gov.uk)

### Clinical aspects

Nicola Lennard  
Medicines & Healthcare products Regulatory Agency  
Tel: 020 7084 3126  
Email: [nicola.lennard@mhra.gsi.gov.uk](mailto: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](mailto: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](mailto: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](mailto:Haz-Aic@wales.gsi.gov.uk)

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