

Medical Device Alert

Ref: MDA/2012/075 Issued: 25 October 2012 at 12:00

Device

All medical devices and medicinal products containing chlorhexidine

Problem

Risk of anaphylactic reaction due to chlorhexidine allergy.

Action by

All medical and nursing staff involved in the use of these devices and medicinal products.

CAS deadlines

Action underway: 22 November 2012

Action complete: 25 January 2013

Note: These deadlines are for systems to be in place to ensure there is continued awareness of this problem.

Action

- Be aware of the potential for an anaphylactic reaction to chlorhexidine.
- Ensure that known allergies are recorded in patient notes.
- Check the labels and instructions for use to establish if products contain chlorhexidine prior to use on patients with a known allergy.
- If a patient experiences an unexplained reaction, check whether chlorhexidine was used or was impregnated in a medical device that was used.
- Report allergic reactions to products containing chlorhexidine to the MHRA.
- Further guidance on anaphylaxis is available from [NICE](#), the [Resuscitation Council](#) and the [AAGBI](#).

Device

A variety of medicinal products and medical devices contain chlorhexidine, including some over-the-counter (OTC) products.

The MHRA does not hold a comprehensive list of products containing chlorhexidine. However, examples of products which contain chlorhexidine are: antiseptic creams, wipes, cleansers and skin preparations; antiseptic mouthwashes, toothpastes and dental implants; eye drops and contact lens solutions; antiseptic lozenges and throat sprays; urinary catheters; central venous catheters; and antimicrobial dressings.

Problem

The MHRA has received a number of reports of anaphylactic reactions following the use of products containing chlorhexidine. Two examples are given below:

- a patient had an anaphylactic reaction when a skin wipe that contained chlorhexidine gluconate was used prior to cannulation. The patient had previously had an anaphylactic reaction whilst under general anaesthetic but at the time the cause of the reaction was unknown.
- it was reported that a patient with a known chlorhexidine allergy, which was noted on his file and on his wristband, suffered a cardiac arrest shortly after a chlorhexidine impregnated central venous catheter was inserted whilst in the operating theatre. He was successfully resuscitated.

There are also other reports of allergic reactions to chlorhexidine published in journals.

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)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

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:

- A&E departments
- All clinical staff
- All departments
- All surgical units
- All wards
- Anaesthetists
- Clinical governance leads
- Dentists
- Haemodialysis units
- Immunologists
- Infection prevention & control directors
- Infection prevention & control teams
- Intensive care units
- IV nurse specialists
- Medical directors
- Medical oncologists
- Nursing executive directors
- Obstetrics and gynaecology departments
- Ophthalmology departments
- Paramedics
- Pharmacists

- Phlebotomists
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Surgeons
- Theatre managers
- Urology departments

Primary care trusts

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

- Community dental practices
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- General dental practitioners
- General practitioners
- Minor injury units
- NHS walk-in centres
- Ophthalmic practices
- Optometrists
- Practice managers

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/075** or **2012/010/003/081/016**

Technical aspects

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Medicines & Healthcare products Regulatory Agency
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Email: sharon.knight@mhra.gsi.gov.uk
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Clinical aspects

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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:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk

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