Safety Notice

Medical Devices

Risks associated with medical devices containing chlorhexidine / chlorhexidine gluconate

Priority 2 – Warning

HPRA Safety Notice: SN201714

<table>
<thead>
<tr>
<th>MANUFACTURER / SUPPLIER</th>
<th>HPRA CASE REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Several devices</td>
<td>MSP22840</td>
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</tbody>
</table>

**ISSUE**

The use of chlorhexidine-containing devices has recently been associated with:

- Serious but rare anaphylactic reactions due to chlorhexidine allergy.
- Severe chemical injury and burns in premature infants.

Examples of medical devices which may contain chlorhexidine include:

- wash cloths, vascular access site dressings, antimicrobial dressings;
- urinary catheters, central venous catheters (CVC), peripherally inserted central venous catheters (PICC lines), needless IV connectors;
- eye drops, contact lens solution, lubricating gels, bladder irrigation solutions;
- dental implants.

Many of these products are available over the counter. Chlorhexidine is an antiseptic and disinfectant that is active against broad spectrum bacteria including MRSA, viruses and fungi.

**ACTION OR RECOMMENDATIONS**

The HPRA advises patients and users:

If you experience symptoms of a serious allergic reaction:

1. stop using the chlorhexidine-containing product immediately and then
2. seek immediate medical attention.
Symptoms of an allergic reaction to chlorhexidine can happen within minutes of exposure. Symptoms may include:

- flushing of the face;
- hives, rash;
- rapid swelling of the face, throat, arms or legs;
- shock;
- wheezing or difficulty breathing;
- collapse or loss of consciousness.

Patients who have any concerns about using chlorhexidine-containing products should speak to their doctor or pharmacist.

**The HPRA advises health care professionals:**

**Allergy and anaphylactic reactions**

- Check patient notes for known allergy to chlorhexidine.
- Always ask patients if they have ever had an allergic reaction to any antiseptic, before using, recommending or prescribing a chlorhexidine-containing device.
- Do not use medical devices containing chlorhexidine on patients with a possible history of an allergic reaction to chlorhexidine.
- Check the labels and instructions for use to establish if products contain chlorhexidine prior to use on patients with a known allergy.
- Use an alternative antiseptic when an allergy to chlorhexidine gluconate is suspected or known.
- Patients using chlorhexidine devices should be made aware that allergic reactions might occur and to seek immediate medical attention if they experience symptoms. This allergy should be documented in their medical notes.

**Chemical injuries**

Bear in mind the risk of severe chemical injuries when using alcohol-based or water-based chlorhexidine solutions on premature infants:

- The risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.
- Some Neonatal Intensive Care Units (NICUs) use chlorhexidine solutions for skin antisepsis prior to invasive procedures such as central and peripheral intravenous access.
- Use the minimum amount of chlorhexidine solution required and do not allow the solution to pool in skin folds or under patients. Remove any excess solution and any soaked materials, drapes, or gowns from the skin.
- Monitor patients closely to detect and manage cutaneous side effects at an early stage.
TARGET GROUPS

<table>
<thead>
<tr>
<th>All clinical staff</th>
<th>Paramedics</th>
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<tr>
<td>All departments</td>
<td>Pharmacists</td>
</tr>
<tr>
<td>All neonatal / paediatric ICU healthcare professionals</td>
<td>Dentists</td>
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<tr>
<td>Surgeons</td>
<td>Risk managers</td>
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<tr>
<td>Anaesthetists</td>
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BACKGROUND

Recent European and American published literature reviews have highlighted the potential for serious allergic reactions to chlorhexidine-containing products including medical devices. These publications highlighted the need to raise awareness of the presence of chlorhexidine in some medical devices and risk of:

- Serious but rare allergic reactions and anaphylactic shock
- Severe chemical injury and burns in premature infants

Further information:


HPRA CONTACT INFORMATION

All adverse incidents relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
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