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Chlorhexidine 7,1% digluconate (CHX) aqueous solution or gel (10ml)

Reports of serious eye injury due to errors in administration

WHO has been made aware of multiple, recent reports of eye injury, including blindness, with the use of chlorhexidine gluconate 7.1%, in nine countries in sub Saharan Africa.

Chlorhexidine gluconate (CHX), available as an aqueous solution or as a gel (delivering 4% chlorhexidine), is used in umbilical cord care, and is listed in the WHO Essential Medicines List[i]. WHO recommends daily chlorhexidine (4%) application to the umbilical cord stump during the first week of life for newborns who are born at home in settings with high neonatal mortality (neonatal mortality rate >30 per 1000). Clean, dry cord care is recommended for newborns born in health facilities, and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance such as cow dung to the cord stump. The use of CHX is being implemented in many countries (South Asia and sub-Saharan Africa) as part of a package of essential newborn interventions to reduce the incidence of omphalitis[ii].

CHX causes serious harm if mistakenly applied to the eyes, resulting in severe eye injuries. Over forty (40) cases of such incorrect administration are recorded, either as media reports, or in the literature, since 2015. Injuries associated with both the liquid and gel (ointment) formulations have been reported when CHX was mistaken for eye drops or ointments.

The present Alert is being issued to warn all stakeholders involved in the umbilical cord care programmes about this potential misadministration and risk of serious injury with CHX. All healthcare professionals, caregivers and others involved in its distribution, use and / or administration are advised to take all necessary measures and precautions to ensure its correct use and administration.

Suggestions to National Neonatal and Reproductive Health Programmes and/or Regulators include the following:

- Assess what products are part of the newborn package and select the optimal primary container/dosage form for CHX or modify the design of the container to distinguish the product from other medicines typically used for newborns.
- Update the product label with appropriate information on the safe use of the product.

- Develop more detailed instructions for users (flyers, posters, pictorials etc.) that are culturally appropriate and easy to understand, to ensure correct use of the product.
- Train health care professionals who interact with mothers and/or provide the product to ensure the full understanding of the indications and contraindications for use and application methods.

All stakeholders are advised to remain alert to incidents of eye injury with CHX in their settings and to report these to their National Regulatory Authority (NRA). Member States are reminded that adverse events associated with the use of any medicinal product should be reported to the National Regulatory Authority.

For any questions relating to this alert please contact Dr S Pal (pals@who.int) or Dr J Simon (simonjo@who.int).

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[i] https://www.who.int/medicines/publications/essentialmedicines/en/

[ii] https://www.who.int/maternal_child_adolescent/documents/postnatal-care-recommendations/en/ (page 3)