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PHV-issue: Chlorhexidin kutane Lösung– Änderungen der Fach- und Gebrauchsinformationen

Sehr geehrte Damen und Herren,

basierend auf einer Routinesignaldetektion kam das Pharmacovigilance Risk Assessment Committee in der Sitzung vom September 2014 zu folgender Empfehlung für alle Chlorhexidin-haltigen kutanen Lösungen.

1. Changes to the SmPC:

4.4 Special warnings and precautions for use

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to [insert product name], care must be taken to ensure no excess product is present prior to application of the dressing.

Section 4.8 (undesirable effects):

Chemical burns in neonates (frequency unknown)



2. Changes to the PL (to be included in the section providing information necessary before using the chlorhexidine product):

Use with care in newborn babies, especially those born prematurely. <Product name> may cause chemical skin burns.

Where tear-off portion exist in leaflets, this information should include the following wording:

Use with care in neonates, especially those born before 32 weeks of gestation and within the first 2 weeks of life. <Product name> may cause chemical skin burns.

Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient.

3. Wording proposed for product labelling of all chlorhexidine products, including those not regulated as medicines:

Use with care in newborn babies, especially those born prematurely. <Product name> may cause chemical skin burns.

The PRAC considered that communication of this important safety issue to relevant hospital physicians, nursing staff and pharmacists responsible for neonatal/ paediatric intensive care units would be important and may be best delivered by means of a communication issued by NCAs . The following key elements were agreed, which could be highlighted in such communications:

- Risk of severe chemical injuries when using alcohol-based or water-based chlorhexidine solutions on preterm 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
- The minimum amount of chlorhexidine solution required should be used and the solution should not be allowed to pool in skin folds or under the patients. Any excess solution and any soaked materials, drapes, or gowns from the skin should be removed
- Patients should be observed closely to detect and manage cutaneous side effects at an early stage.

Finally, the PRAC agreed that MAHs of chlorhexidine cutaneous solutions should strengthen their pharmacovigilance activities in terms of closely monitoring cutaneous adverse events in neonates through signal detection and literature monitoring.