

March 24, 2026

**Chlorhexidine Acetate B.P. 0.05% w/v for Irrigation - MA1277/03902:  
Important update regarding the use of Chlorhexidine Acetate.**

Dear Healthcare Provider or Distributor

Baxter Healthcare Corporation, in agreement with the Malta Medicines Authority, would like to inform you of the following important updates made to the Product Information Leaflet (PIL).

**Summary:**

- The product information in the Package Leaflet (PL) for Chlorhexidine Acetate 0.05% w/v Irrigation Solution was updated with an additional warning :
- **Chlorhexidine must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly. Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).**
- **The specific batches listed in the table below do not contain this updated verbiage in the PIL.**
- **Chlorhexidine Acetate 0.05% w/v for Irrigation Solution is for general topical use, combining antibacterial activity against a wide range of vegetative gram-positive and gram-negative bacteria with useful cleansing properties. The solution is recommended for general topical use when antibacterial irrigation is indicated, including wound and burn irrigation.**

**Affected Product**

Product Code	Description	GTIN	Lot Number	Expiration Date
FKF7984J	Chlorhexidine Acetate B.P. 0.05% w/v for Irrigation	<b>Carton GTIN Number:</b> 5413760154213	24J24BB1A	28-Sep-2026
			24J24BB1B	28-Sep-2026
			24L16BB1B	28-Nov-2026

**Background**

The Pharmacovigilance Risk Assessment Committee (PRAC) of European Medicines Agency (EMA) did recommend that all MAHs of chlorhexidine containing products indicated for skin disinfection and intended for cutaneous use should amend the product information to include the risk for permanent corneal injury following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of beyond the intended surgical preparation area. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure.

If you distribute this product to other facilities or to departments within your institution, please forward a copy of this communication to those locations.

## Call for reporting

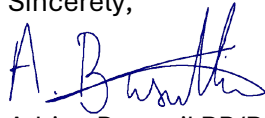
If you become aware of an adverse event involving any product of Baxter Healthcare please report in accordance with the national requirements via the national spontaneous reporting system, to:

### Malta

ADR Reporting Website: <https://medicinesauthority.gov.mt/adrportal>

Any adverse reactions experienced with the use of these products may be reported to: [vigilanceuk@baxter.com](mailto:vigilanceuk@baxter.com)

Sincerely,



Adrian Busuttill RP/Regulatory Affairs Manager  
Drugsales Ltd Baxter Healthcare representative and distributor in Malta