HEXI PREP™

PRESCRIBING INFORMATION

Prescribing information: HEXI PREP 2% w/v / 70% v/v for cutaneous use. Refer to Summary of Product Characteristics before prescribing. **Presentation:** Each impregnated pad contains 1.5mL or 3.0mL of HEXI PREP solution. One mL of solution contains 20mg chlorhexidine digluconate and 0.7mL of isopropyl alcohol. Also contains water. **Indication:** Disinfection of the skin prior to invasive medical procedures that do not require a clean air environment. **Dosage & administration:** There are two pad sizes available. HEXI PREP may be used on all age groups and patient populations. Use with care in newborn babies, especially those born prematurely. The choice of pad size will depend on the size of the area to be disinfected, the invasive procedure and the clinician's preference. For both non-sterile and sterile procedures, the user should wear gloves during application. Keep the pad folded and press firmly against the skin on the intended area and wipe back and forth for a total of 30 seconds. Allow to air dry completely. It is recommended that HEXI PREP solution remains on the skin post-procedure to provide continued antimicrobial activity. If removal is necessary, remove with soap and water or alcohol. **Contraindications:** The medicinal product is contraindicated where patients have shown previous hypersensitivity to chlorhexidine or isopropyl alcohol. **Warnings & precautions:** The solution is flammable. Do not use with electrocautery procedures or other ignition sources until dry. Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not allow the solution to pool in skin folds or under the patient or drip onto sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to HEXI PREP, care must be taken to ensure no excess product is present prior to application of the dressing. For external use only on intact skin. Do not use on open skin wounds. Avoid prolonged contact with the skin. Do not use on broken or damaged skin. Avoid contact with neural tissue, the middle ear, the eyes and mucous membranes. Chlorhexidine-containing products are known causes of anaphylactic reactions during anaesthesia. The symptoms of anaphylactic reactions might be masked in an anaesthetised patient. If symptoms of an anaphylactic reaction are detected during anaesthesia, chlorhexidine-related allergic reactions should be considered. When chlorhexidine-related reaction during anaesthesia is suspected, other products containing chlorhexidine used during anaesthesia (e.g., IV lines) should be removed. Special precaution should be taken to avoid patient exposure to any other product containing chlorhexidine during the course of the treatment. The use of chlorhexidine solutions, both alcohol–based and aqueous, for skin antisepsis prior to invasive medical 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. **Pregnancy & lactation:** There are no studies with this product in pregnant or lactating women. No effects during pregnancy are anticipated since systemic exposure to chlorhexidine digluconate is negligible. HEXI PREP can be used during pregnancy. No effects on the breastfed newborn infant are anticipated since the systemic exposure of breastfeeding women to chlorhexidine digluconate is negligible. HEXI PREP can be used during lactation. **Undesirable effects:** Skin disorders: very rare allergic or irritation skin reactions have been reported with chlorhexidine and isopropylalcohol: erythema, rash (e.g., erythematous, papular or maculopapular), pruritus and blisters or application site vesicles. Other local symptoms have included skin burning sensation, pain and inflammation. Frequency not known: dermatitis, eczema, urticaria, chemical burns in neonates. Immune disorders: Frequency unknown: Hypersensitivity including anaphylactic shock. Cases of anaphylactic reactions have been reported during anaethesia. Common reported reactions: associated with site reactions often within the area of application and very rarely spread. This product may cause a severe allergic reaction. Symptoms may include wheezing / difficulty breathing, shock, facial swelling, hives or rash. Use of HEXI PREP is contraindicated where patients have shown previous hypersensitivity to chlorhexidine or isopropyl alcohol. If hypersensitivity or an allergic reaction occurs, stop use and seek medical help right away. **Reporting adverse events:** Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GAMA Healthcare Ltd. **Per pad costs** (NHS Supply Chain; ex VAT): HEXI PREP(CHEX15) 1.5 ml UK £0.28, HEXI PREP (CHEX30) 3.0 ml UK £0.66. **Legal category:** UK GSL. **Marketing Authorisation Numbers:** HEXI PREP (PL 40867/0002). **Marketing Authorisation Holder:** GAMA Healthcare Ltd., Maylands Building, Maylands Avenue, Hemel Hempstead Industrial Estate, Hemel Hempstead, Hertfordshire, HP2 7TG. **Date of issue:** August 2025.

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