



BAXEDIN® 0.05%

CHLORHEXIDINE GLUCONATE

0.05% (1:2000) W/V

with 4% v/v Isopropyl Alcohol (IPA) or without preservative

THERAPEUTIC CLASSIFICATION

Sterile Aqueous Antiseptic Solution

ACTION AND CLINICAL PHARMACOLOGY

Chlorhexidine is a bactericidal antiseptic effective against a large range of vegetative gram positive and gram negative bacteria, although more effective against gram positive bacteria. Some species of *Pseudomonas* and *Proteus* are relatively less susceptible. Chlorhexidine is ineffective against acid-fast bacteria, bacterial spores, fungi and viruses.

As a cationic material, chlorhexidine is incompatible with soaps and other anionic materials.

At a concentration of 0.05% chlorhexidine is incompatible with borates, bicarbonates, carbonates, chlorides, citrates, phosphates and sulfates, forming salts of low solubility which may precipitate from solutions after standing.

Chlorhexidine is most active at a neutral pH; its activity is reduced by organic matter (blood, serum, etc.) and by phospholipids.

INDICATIONS AND CLINICAL USE

BAXEDIN® 0.05% is well tolerated by the skin and the vaginal epithelium and is indicated for:

- Disinfection of skin, tissues, wounds and abrasions;
- Use in sitz baths;
- In obstetrics for disinfection of the skin.

The solution is ready for use; do not dilute.

Does not contain any surfactant or coloring agent.



CONTRAINDICATIONS

Patients who have previously experienced a hypersensitivity to chlorhexidine (such reactions are extremely rare).

WARNINGS

For external use only. Keep out of the eyes and avoid contact with brain, meninges or middle ear. Do not use in body cavities. If chlorhexidine solutions come into contact with eyes, wash out promptly and thoroughly with water. Do not use the solution in the eyes before or after ophthalmic surgery. If accidental contact is suspected, wash thoroughly with sterile water before starting surgical procedure.

Keep away from children.

PRECAUTIONS

Fabrics which have been in contact with chlorhexidine may develop a brown stain if bleached with a hypochlorite. Perborate bleach may be used instead.

ADVERSE REACTIONS

Skin irritation may occasionally occur. Generalized allergic reactions to chlorhexidine have been reported, but are extremely rare.

TREATMENT OF OVERDOSAGE

Chlorhexidine taken orally is poorly absorbed. In case of oral absorption of large doses, treat with gastric lavage using milk, egg white, gelatin and mild soap. Employ supportive measures as appropriate. Blood transfusions may be necessary to counteract haemolysis.

DIRECTIONS FOR USE

Apply locally twice daily or as directed by the physician.



PHARMACEUTICAL INFORMATION

RAW MATERIAL

Proper name:

Chlorhexidine gluconate solution.

Chemical name:

1,1'-hexamethylene bis-[5-(4-chlorophenyl) biguanide] digluconate

Chemical formula:

$C_{22}H_{30}Cl_2N_{10} \cdot 2 C_6H_{12}O_7$

Molecular weight:

897.8

Physical form:

Almost colorless, clear or not more than slightly opalescent liquid, odorless.

Solubility:

Miscible with water, with not more than 5 parts of 96% ethyl alcohol and with not more of 5 parts of acetone.

STABILITY AND STORAGE RECOMMENDATIONS

Store at a temperature between 4 and 25°C in tightly closed containers and protect from light. The solution containing Isopropyl Alcohol remains stable for 30 days after the bottle has been opened. The product is no longer sterile once the bottle has been opened.

SUPPLIED

BAXEDIN® 0.05% with 4% IPA is available in plastic bottles of 110-mL (Product code: L0000006), 500 mL (Product code: L0000001) and 1-L (Product code: L0000004).

BAXEDIN® 0.05% without preservative is available in plastic bottles of 110-mL (Product code: L0000007).

Each mL contains 0.05% w/v Chlorhexidine Gluconate, 4% v/v Isopropyl Alcohol as a preservative (if applicable) in Purified Water.

BAXEDIN® 0.05% contains 0.05% Chlorhexidine Gluconate (w/v) in Purified Water and, if applicable, 4% (v/v) Isopropyl Alcohol as a preservative.

Does not contain any coloring agent, paraben, sulfite or tartrazine.

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V-02

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