



BAXEDIN® 2% - 70%

CHLORHEXIDINE GLUCONATE 2% W/V and Isopropyl alcohol 70% v/v

TINTED OR UNTINTED SOLUTION

THERAPEUTIC CLASSIFICATION

Aqueous Antiseptic Solution

ACTIONS AND CLINICAL PHARMACOLOGY

Chlorhexidine is a bactericidal antiseptic effective against a large range of vegetative gram positive and gram negative bacteria, but it is 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 2%, 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® 2% - 70% is indicated:

- As a cutaneous preoperative antiseptic;
- As a cutaneous antiseptic for catheter site care.

BAXEDIN® 2% - 70% tinted contains a coloring agent to help identify the disinfected area.

CONTRAINDICATIONS

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



WARNINGS

For professional and external use only. Do not use on broken skin. Avoid contact with brain, meninges or middle ear. Do not use in body cavities. Avoid contact with eyes. In case of accidental contact with eyes, rinse with water. If irritation develops or increases, use of the product should be discontinued. If irritation persists for more than 5 days, consult a doctor.

Discontinue if irritation develops.

Keep out of reach of children.

CAUTION: FLAMMABLE PRODUCT.

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 irritations 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 hemolysis.

DIRECTIONS FOR USE

As directed by physician.

After skin antiseptics, use sterile towels to blot up any accumulation of solution.

FLAMMABLE LIQUID: Remove all material that becomes soaked with the alcohol solution. Wait until the solution dries before using equipment that can produce flames or spark.



PHARMACEUTICAL INFORMATION

RAW MATERIALS

Proper name:

Chlorhexidine gluconate solution

Chemical name:

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

Chemical formula:

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

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.

Proper name:

Isopropyl alcohol

Chemical name:

2-propanol; Isopropanol.

Chemical formula:

C_3H_8O

Molecular weight:

60.1

Physical form:

Clear liquid. Typical odor.

Solubility:

Miscible with water, alcohol, ether, chloroform.

STABILITY AND STORAGE RECOMMENDATIONS

Store at a temperature between 4 and 25°C in tightly closed containers and protect from light. The solution remains stable for the duration of its shelf-life after the bottle has been opened.

SUPPLIED

BAXEDIN® 2% - 70% tinted is available in plastic bottles of 110-mL (Product code: L0000011) and 500-mL (Product code: L0000018).

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BAXEDIN® 2% - 70% untinted is available in plastic bottles of 500-mL (Product code: L0000017).

BAXEDIN® 2% - 70% contains Chlorhexidine Gluconate 2% (w/v) and Isopropyl alcohol 70% (v/v) and does not contain any surfactant.

Does not contain parabens, sulfites or tartrazine.

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