



BAXEDIN® 20%

CHLORHEXIDINE GLUCONATE, BP 20% W/V (CONCENTRATED STOCK SOLUTION)

DILUTE BEFORE USE

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.

Chlorhexidine is incompatible with borates, bicarbonates, carbonates, chlorides, citrates, phosphates and sulfates, forming salts of low solubility which may precipitate from solution 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® 20% must always be diluted before use.

Baxedin® 20% only contains 20% chlorhexidine (w/v) without any surfactant.

Hospital setting

General disinfection and skin cleansing.

Preoperative skin preparation.

Preoperative hand scrub.

Prolonged storage of sterile instruments.

Emergency disinfection of clean medical and surgical instruments.

Disinfection of respiratory and anesthetic equipment.



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

Preparation of Diluted Solutions

| INDICATIONS | DESIRED CONCENTRATION | MODE OF PREPARATION |
|--|---------------------------------|--|
| General disinfection and skin cleansing | 2% aqueous alcoholic solution | Add distilled water to 70 mL of 70% Isopropyl Alcohol and 100 mL of Baxedin® 20% to make 1 L of 2% solution. |
| Preoperative Skin Preparation | 0.5% alcoholic solution | Add 70% Isopropyl Alcohol to 25 mL of Baxedin® 20% to make 1 L of 0.5% solution. |
| Preoperative Hand Scrub | 4% aqueous alcoholic solution | Add distilled water to 70 mL of 70% Isopropyl Alcohol and 200 mL of Baxedin® 20% to make 1 L of 4% solution. |
| Emergency Disinfection of Clean Medical and Surgical Instruments | 0.5% alcoholic solution | Add 70% Isopropyl Alcohol to 25 mL of Baxedin® 20% to make 1 L of 0.5% solution. |
| Disinfection of Respiratory and Anesthetic Equipment | 0.1% aqueous solution | Add distilled water to 5 mL of Baxedin® 20% to make 1 L of 0.1% solution. |
| Hand disinfection of kitchen workers and food plant workers. General disinfection of premises and food manipulation areas of food plants. | 0.1% aqueous alcoholic solution | Add distilled water to 5 mL of Baxedin® 20% and 55 mL of 70% Isopropyl Alcohol and to make 1 L of 0.1% solution. |

Dilution to a 0.05% chlorhexidine solution

If a solution without IPA is desired, dilute directly with distilled water.

For a one litre (1-L) solution:

- 1) Use 2.5 mL of Baxedin® 20%;
- 2) Add 60 mL of 70% Isopropyl Alcohol; and
- 3) Complete the volume to 1-L with distilled water.

For a 500-mL solution:

- 1) Use 1.25 mL of Baxedin® 20%;
- 2) Add 30 mL of 70% Isopropyl Alcohol; and
- 3) Complete the volume to 500-mL with distilled water.



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 between 4°C and 25°C. Keep tightly closed and protect from light.

Only glass, high density polyethylene or polypropylene containers must be used to store diluted Baxedin® 20% solutions.

Diluted solutions of Baxedin® 20% must be used within one day (24 hours) of their preparation.

SUPPLIED

BAXEDIN® 20% is available in plastic bottles of 500-mL (Product Code: L0000005).

Does not contain alcohols, parabens, sulfites or tartrazine.

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