



BAXEDIN® PRE-OP

**CHLORHEXIDINE GLUCONATE
0.5% W/V in 70% Isopropyl Alcohol**

TINTED OR UNTINTED SOLUTION

THERAPEUTIC CLASSIFICATION
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, 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 0.5% 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® PRE-OP is indicated:

- For skin asepsis prior to surgery;
- As a disinfectant.

BAXEDIN® PRE-OP 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 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.

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

Local application as directed by physician.

PHARMACEUTICAL INFORMATION

RAW MATERIAL

Proper name:

Chlorhexidine gluconate solution.

Chemical name:

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

Chemical formula:

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

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

BUREAU CHEF: 11,177 RUE HAMON, MONTRÉAL (QUEBEC) H3M 3E4 • TEL.: (514) 335-0310 FAX: (514) 339-1407

HEAD OFFICE:

LABORATOIRES: 10,850 RUE HAMON, MONTRÉAL (QUÉBEC) H3M 3A2

LABORATORIES: 11,911 MACHRINA WAY, UNIT 6, RICHMOND, B.C. V7A 4V3 • TEL.: (604) 271-6228 FAX: (604) 271-4742



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® PRE-OP tinted is available in plastic bottles of 500 mL (Product code: L0000003).

BAXEDIN® PRE-OP untinted is available in plastic bottles of 500 mL (Product code: L0000015).

BAXEDIN® PRE-OP contains 0.5% (w/v) chlorhexidine in 70% (v/v) isopropyl alcohol without any surfactant.

Does not contain parabens, sulfites or tartrazine.

Omega Laboratories Limited

Montréal, Canada H3M 3A2

V-01