



STANHEXIDINE® 2% AQUEOUS

CHLORHEXIDINE GLUCONATE

2% W/V

with 4% v/v Isopropyl Alcohol (IPA)

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, 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 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

STANHEXIDINE 2% AQUEOUS is an anti-bacterial for the skin and is indicated for the treatment of superficial skin infection.

The solution is ready for use; do not dilute.

Does not contain any surfactant.

CONTRAINDICATIONS

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

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



WARNINGS

For external use only. Keep out of the eyes and avoid contact with brain, meninges or middle ear. If eyes are accidentally splashed, they should be promptly and thoroughly rinsed with water. Prolonged contact may cause eye damage. Do not use in body cavities. Do not inject. If accidental contact is suspected, wash thoroughly with sterile water before starting surgical procedure.

Keep away from children.

If swallowed accidentally, induce vomiting immediately. Administer milk or egg white. Contact a physician.

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. If swallowed accidentally, induce vomiting immediately. Administer milk or egg white. Contact a physician.

Blood transfusions may be necessary to counteract haemolysis.

DIRECTIONS FOR USE

Apply a small amount of STANHEXIDINE® 2% AQUEOUS with 4% IPA. FOR EXTERNAL USE ONLY.

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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 remains stable for 30 days after the bottle has been opened.

SUPPLIED

STANHEXIDINE 2% AQUEOUS is a clear blue solution available in plastic bottles of 450 mL (Product Code: L0000009).

STANHEXIDINE 2% AQUEOUS contains 2% Chlorhexidine Gluconate (w/v), 4% (v/v) Isopropyl Alcohol as a preservative and blue FD&C n°1 in Purified Water.

Does not contain any paraben, sulfite or tartrazine.

Omega Laboratories Limited

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