

PACKAGE INSERT TEMPLATE FOR CHLORHEXIDINE GLUCONATE

Brand or Product Name

[Product name] liquid/Solution

Name and Strength of Active Substance(s)

Chlorhexidine Gluconate w/v , v/v or w/w [0.5-5%]

Product Description

*[Visual description of the appearance of the product (eg colour, texture, odour,etc)]
eg red viscous liquid with a citrus fragrance and practically free from extraneous material*

Pharmacodynamics

Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.

Pharmacokinetics

Chlorhexidine is cationic nature, it binds strongly to skin mucosa and other tissues and is thus very poorly absorbed. There are, as a consequence, no general pharmacological studies on chlorhexidine available and its effects on internal organs are minimal. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

Indication

Chlorhexidine Gluconate liquid/solution

To be used for general antiseptic purpose such as for pre-operative skin disinfection and hand washing, disinfection of wounds, burns or other skin damage or disorders.

Recommended Dosage

Adult Dosage

Hand washing: Wet hands and forearms, apply 5ml of Chlorhexidine Gluconate solution and wash for 30 seconds. Rinse thoroughly and dry.

Body washing/showering: Apply 25ml of Chlorhexidine Gluconate solution on the hand, add water, work into lather, wash as usual and rinse thoroughly.

Pre-operative Surgical Hand Disinfection: Wet the hands and forearms, apply 5 ml of Chlorhexidine Gluconate solution and wash for 1 minute cleaning the fingernails with a brush or scraper. Rinse and apply a further 5 ml of Chlorhexidine Gluconate solution and continue washing for a further two minutes. Rinse thoroughly and dry.

Pediatric Dosage

General skin cleansing : rinse area to be cleansed with water, apply minimum amount of Chlorhexidine Gluconate solution necessary to cover skin or wound area and wash gently, then rinse.

Mode of Administration

Topical liquid/solution.

Contraindications

Risk-benefit should be considered when hypersensitivity to Chlorhexidine exist.

Warnings and Precautions

For external use only. Avoid contact with brain, meninges and middle ear. If there is contact with these areas, rinse out promptly and thoroughly with water. Keep out of eyes. If chlorhexidine solutions come into contact with eyes, wash out promptly and thoroughly with water. The antimicrobial activity of chlorhexidine may be diminished through incompatibility or through adsorption. Its activity may also be reduced in the presence of organic matter such as blood and pus. Do not use in body cavities.

Interactions with Other Medicaments

The cationic nature of the compound results in activity being reduced by soap and anionic compounds as they can form insoluble salts. Anions to be wary of include borates, bicarbonates, carbonates, chlorides, citrates, nitrates, phosphates and sulphates with due attention being paid to the presence of hard water.

Statement on Usage During Pregnancy and Lactation

Pregnancy and lactation

No special precautions need to be taken when used in pregnancy and lactation.

Adverse Effects / Undesirable Effects

Hypersensitive to Chlorhexidine Gluconate. Topical exposure to Chlorhexidine Gluconate can cause sensitization , anaphylactic shock with urticaria and dyspnoea. It also can cause deafness when instilled in the middle ear through perforated ear drums. Other adverse effects include irritation, sensitisation and generalised allergic reactions have been reported with Chlorhexidine containing products, especially in the genitals areas.

Overdose and Treatment

Chlorhexidine Gluconate taken orally is poorly absorbed into the blood. Accidental ingestion may require gastric lavage using milk, egg white, gelatin or mild soap. Employ supportive measures as

appropriate. Haemolysis has been reported following ingestion or accidental intravenous administration. Haemolysis may necessitate blood transfusion.

Storage Conditions

[Store below 30° C, protect from light and moisture]

Dosage Forms and Packaging Available

[Packaging type & pack size]

Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]