

PROFESSIONAL INFORMATION

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

CHLORHEXIDINE GLUCONATE HANDRUB ADCO (Disinfectant Solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CHLORHEXIDINE GLUCONATE HANDRUB ADCO contains chlorhexidine gluconate solution diluted to chlorhexidine gluconate 0,5 % w/v.

Excipient(s) with known effect:

Ethyl alcohol 70 % v/v

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Disinfectant Solution

A light pink coloured clear liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is indicated for the disinfection of surgeons' hands prior to operative procedure and general hand disinfection.

4.2 Posology and method of administration

Posology

For external use only after washing and drying hands. For hand disinfection use approximately 2 ½ ml CHLORHEXIDINE GLUCONATE HANDRUB ADCO and rub well into hands until dry. For pre-operative preparations use approximately 5 ml CHLORHEXIDINE GLUCONATE HANDRUB ADCO and rub well into hands and forearms until dry, use sterile nail brush for fingernails. Repeat process.

Method of administration

For external use only

4.3 Contraindications

Hypersensitivity to chlorhexidine gluconate, ethyl alcohol or to any of the excipients listed in section 6.1

The solution is an irritant to eyes and mucous membranes. It should therefore be kept away from these areas. If the solution comes in contact with the eyes, they should be washed promptly and thoroughly with water.

4.4 Special warnings and precautions for use

For external use only.

The solution is flammable. Keep out of reach of children.

Hypersensitivity Reactions

Chlorhexidine Acetate contains chlorhexidine, which is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock, which can be fatal. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. This product should not be administered to anyone with a

potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

If any signs or symptoms of a suspected hypersensitivity reaction develop, immediately stop use. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Chemical Burns in Neonates and Paediatric Patients

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with skin reactions such as chemical burns in neonates. This risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to chlorhexidine, care must be taken to ensure no excess product is present prior to application of the dressing.

Preoperative Skin Preparation

Caution should be exercised when chlorhexidine is used in preoperative skin preparations for face or head (See Section 4.3 Contraindications).

4.5 Interactions with other medicines and other forms of interaction

The activity of chlorhexidine as in CHLORHEXIDINE GLUCONATE HANDRUB ADCO is reduced or neutralized by an alkaline pH, the presence of organic matter, anionic detergents, and tannins.

4.6 Fertility, pregnancy and lactation

There are no studies with this product in pregnant or lactating women.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine is negligible.

Lactation

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of the breast-feeding woman to CHLORHEXIDINE GLUCONATE HANDRUB ADCO is negligible.

Fertility

The effects of Chlorhexidine Gluconate on human reproduction have not been studied.

4.7 Effects on ability to drive and use machines

CHLORHEXIDINE GLUCONATE HANDRUB ADCO has no influence on the ability to drive and use machines.

4.8 Undesirable effects**a. Summary of the safety profile**

Skin sensitivity to chlorhexidine as in CHLORHEXIDINE GLUCONATE HANDRUB ADCO and ototoxicity may occur (see section 4.3).

b. Tabulated summary of adverse reactions

System Organ Class	Frequency	Adverse event
Immune system disorders	Frequency unknown	Hypersensitivity reactions including anaphylactic shock and anaphylactoid reactions manifested by cardiac arrest, circulatory collapse, hypotension, bronchospasm, tachycardia, rash, erythema and urticaria
Skin and subcutaneous tissue disorders	Frequency unknown	Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters
Other adverse reactions	Frequency unknown	Chemical burns in neonates

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email

Adcock.aereports@adcock.com

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (See section 4.8).

Overdose of chlorhexidine may constitute a medical emergency.

In case of accidental ingestion or overdose, seek immediate medical attention.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group and ATC code: Antiseptics and Disinfectants, ATC Code D08AC02

5.1 Pharmacodynamic Properties

Mechanism of action

Chlorhexidine Gluconate is a biguanide with antiseptic activity. It is effective against both Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted with CHLORHEXIDINE GLUCONATE HANDRUB ADCO.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl Alcohol

Glycerine

Carmosine (CI 42510 colour)

Spring awakening Flavour (P 1475 flavour)

Purified Water

6.2 Incompatibilities

CHLORHEXIDINE GLUCONATE HANDRUB ADCO is incompatible with soap and other anionic materials.

6.3 Shelf life

24 months from date of manufacture

6.4 Special precautions for storage

Store at or below 25°C

Protect from heat and light.

Keep away from flame.

Keep bottle closed when not in use.

6.5 Nature and contents of container

CHLORHEXIDINE GLUCONATE HANDRUB ADCO is supplied in a 500 ml white cylindrical HDPE bottle with a white cap which is induction sealed. 20 bottles of 500 ml are packed in a single layer in corrugated printed shippers, which are partitioned.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER(S)

55/13.1/0755

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6 June 2023

10. DATE OF REVISION OF THE TEXT

6 June 2023