

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name: Hexicord Topical Solution

1.2 Strength: Chlorhexidine Gluconate 7.1% w/v

1.3 Pharmaceutical Dosage Form: Topical Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hexicord contains 7.1% w/v Chlorhexidine Gluconate equivalent to 35.52 ml Chlorhexidine Gluconate solution BP or 4 g / 100 ml (4% w/v) Chlorhexidine solution.

For full list of excipients, see section 6.1 of SmPC

3. PHARMACEUTICAL FORM

Topical solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hexicord is used to prevent umbilical cord care of newborns.

4.2 Posology and method of administration

According to WHO recommendation, Chlorhexidine Gluconate (HEXICORD) should be applied to the umbilical cord stump during the first week of life for newborns and Chlorhexidine Gluconate is listed in the WHO Essential Medicines List.

Apply the Chlorhexidine Gluconate (HEXICORD) Solution to the umbilical cord stump during on the day of birth, followed by once daily applications ranging from 7 to 14 days of post birth or as advised by registered physician.

Use Chlorhexidine Gluconate (HEXICORD) Solution immediately after cord cutting and keep the cord clean and dry. Before using this medication, read the below steps and follow the instructions carefully.

Step-1: Before applying the Chlorhexidine Gluconate Solution; wash the hands with clean water and soap and let hands dry with air after washing.

Step-2: Squeeze the bottle to apply the Chlorhexidine Gluconate Solution to the tip of the umbilical cord, the stump of the umbilical cord and base of umbilical cord.

4.3 Contraindications

Chlorhexidine Gluconate is contraindicated in patients with known hypersensitivity to Chlorhexidine Gluconate or any components of this product.

4.4 Special warnings and precautions for use

For external use only. If the medication comes into contact with the eyes, wash out promptly and thoroughly with clean water. Do not swallow or inject the medication. Do not use this medicine in the ears and over large areas of the body. Do not use this medication in the eyes because it may cause blindness.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents. Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing Chlorhexidine.

4.6 Fertility, Pregnancy and lactation

No none restriction.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The most common side effects are allergic skin reactions such as erythema and skin irritation.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose

Accidental Ingestion: Chlorhexidine taken orally is poorly absorbed. Since there is very little absorption of Chlorhexidine in the digestive tract, accidental ingestion is very unlikely to cause systemic effects. Symptoms of an overdose resemble those of alcohol intoxication (drunkenness). Nausea, vomiting, slurred speech, a staggering walk, and drowsiness may develop. In the case of massive ingestion gastro-intestinal irritation may be observed, and also hepatotoxicity. Give a glass of milk or water and employ supportive measures as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is an effective antiseptic with a wide range of activity against micro-organisms, including gram positive and gram-negative bacteria, fungi and viruses.

5.2 Pharmacokinetic properties

Chlorhexidine Gluconate has a broad spectrum bactericidal and bacteriostatic activity against Gram positive bacteria, Gram negative bacteria and fungi. Chlorhexidine Gluconate reacts with the microbial cell surface to destroy the integrity of the cell membrane. Then it penetrates into the cell and precipitates the cytoplasm, and the cell dies. In vitro, Chlorhexidine Gluconate can kill nearly 100% of Gram positive and Gram-negative bacteria within 30 seconds.

5.3 Preclinical safety data

Chlorhexidine is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%)
Sodium Hydroxide
Gluconolactone
Purified Water

6.2 Incompatibilities

Chlorhexidine is incompatible with soap and other anionic agents.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a cool (below 30°C) and dry place, protect from light.

6.5 Nature and contents of container

10 ml plastic dropper bottle.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

ADVANCED CHEMICAL INDUSTRIES PLC.
P.O. BOX- 7218,
245 TEJGAON INDUSTRIAL AREA
DHAKA-1208, BANGLADESH

8. MARKETING AUTHORISATION NUMBER

H2022/CTD7953/16239

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION

13.10.2022

10. DATE OF REVISION OF THE TEXT

Not applicable