**Professional Information for Medicines for Human Use**

**SCHEDULING STATUS**

**S0**

## 1. NAME OF THE MEDICINE

**CETIDINE CONCENTRATE** (Liquid)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL aqueous solution which contains

Chlorhexidine gluconate solution 1,50 % *w/v*

Cetrimide Solution 15,00 % *w/v*

*Preservative*

Isopropanol 4,00 % *v/v*

*Excipients with known effect:*

**Contains Tartrazine**

For full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Liquid

Clear, orange liquid that foams when shaken with a pine odour.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Cleansing physically contaminated wounds and burns.

For external use only.

### 4.2 Posology and method of administration

**1 in 100 aqueous dilution (10mL made up to 1 litre with water)**

Cleansing/disinfection of post-operative wounds. Management of burns. Swabbing in obstetrics, gynaecology and urology.

**1 in 30 aqueous dilution (33mL made up to 1 litre with water)**

Cleansing and disinfection of physically contaminated wounds where extra detergency and anti-microbial effects are indicated. Management and burns where this higher strength is indicated.

**1 in 30 in 70% alcohol (33mL with 200mL water made up to 1 litre with 95% alcohol or white industrial methylated spirits)**

Skin disinfection for pre-operative and other invasive procedures.

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the ingredients. excipients listed in section 6.1.
- Cetidine Concentrate should not come into contact with the eyes, brain, meninges or middle ear.
- Do not use in body cavities.

### 4.3 Special warnings and precautions for use

Cetidine Concentrate contains Tartrazine and may cause allergic reaction.

Cetidine Concentrate should not be applied to the skin in excessive amount either undiluted or diluted, and wet dressings should not be left in contact as hypersensitivity may occur. Discontinue use if hypersensitivity reactions develop.

Hypochlorite bleaches may cause brown stains to develop in fabrics which have been in contact with Cetidine Concentrate solutions. An oxidising bleach such as sodium perborate should be used in laundering.

Cetidine is incompatible with anionic agents and its activity is reduced in the presence of organic matter and soap.

Do not use around the ears, eyes, nose or mouth to avoid contact with the eardrum, eyes and mucous membranes.

Do not use in body cavities.

### 4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

### 4.6 Fertility, pregnancy, and lactation

There are no studies have been established in pregnant or lactating women.

**4.7 Effects on ability to drive and use machines.**

Cetidine Concentrate is for external use only and is not expected to have an effect on the ability to drive and use machinery.

**4.8 Undesirable effects**

| System Organ Class | Frequency Category | Undesirable effects |
|---|---|---|
| **Skin and subcutaneous tissues disorders** | Frequency not known | Idiosyncratic skin reactions may occur. |
| **Immune system disorders** | Less Frequent | Hypersensitivity including anaphylactic |
| **Ear and labyrinth disorders** | Frequency not known | Ototoxicity |

***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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

**4.9 Overdose**

Accidental ingestion could cause nausea and vomiting, dyspnoea and cyanosis due to paralysis of respiratory muscles, possibly leading to asphyxia. Depression of the central nervous system with convulsions, hypotension and coma may occur. Treatment is symptomatic and supportive. Emesis and lavage should be avoided because of the irritant properties of Cetrimide.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

13.1Antiseptics, Disinfectants and Cleansing agents

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**

13.1 Antiseptics, Disinfectants and Cleansing agents

Chlorhexidine, combination-Pharmacotherapeutic group: Antiseptic and disinfectants,

ATC code: D08AC52

***Mechanism of action***

Cetidine Concentrate has cleansing and detergent properties.

Chlorhexidine gluconate is a bisbiguanide antiseptic and disinfectant that provides antiseptic and antimicrobial effects with rapid bactericidal action against wide range of Gram-positive and Gram-negative bacteria. It precipitates the bacterial cytoplasm and it also interferes with membrane function by inhibiting oxygen utilization leading to a decrease in cellular ATP levels. These forms of destabilization lead to the destruction of the cell's integrity and eventually causing cell death. In Gram-negative bacteria, chlorhexidine affects the outer membrane allowing the release of periplasmic enzymes. The inner membrane of these organisms is not ruptured but the uptake of small molecules is impaired. At low concentrations, chlorhexidine exhibits a bacteriostatic effect, while at high concentrations, it is bactericidal. Chlorhexidine has bacteriostatic, bactericidal, fungicidal, fungistatic and some virucidal activity.

Cetrimide is a quaternary ammonium compound (QAC) is antiseptic against bacterial cells involves a general perturbation of lipid bilayer membranes as found to constitute the bacterial cytoplasmic membrane and the outer membrane of Gram-negative bacteria. Such action leads to a generalised and progressive leakage of cytoplasmic materials. Low concentrations of QAC bind firmly to anionic sites found on the membrane surface, causing cells both to lose osmoregulatory capability and to leak potassium ions and protons. Cetrimide is a QAC with actions typical of cationic surfactants. These surfactants dissociate in aqueous solution into a relatively large and complex cation that is responsible for the surface activity and a smaller inactive anion. In addition to emulsifying and detergent properties, QAC have bactericidal activity against Gram-positive bacteria and, at a higher concentration against some Gram-negative bacteria.

## 5.2 Pharmacokinetic properties

When used topically, the N-chlorinated derivative of chlorhexidine binds covalently to proteins in the skin and mucosa and results in a persisting antimicrobial effect with limited systemic absorption. Chlorhexidine can be absorbed through intact skin although there is no suggestion that chlorhexidine gluconate accumulate in the blood with repeated exposures.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Pine Oil

Purified Water (Solvent)

Yellow Tartrazine

Carmosine Red Dye

### 6.2 Incompatibilities

Cetidine Concentrate is incompatible with anionic agents.

### 6.3 Shelf life

24 months at or below 25°C.

### 6.4 Special precautions for storage

Store in a cool place, at or below 25°C.

### 6.5 Nature and contents of container

Clear solution, foams on shaking in a 5L HDPE bottle with a HDPE cap.

## 7 Holder Of Certificate of Registration

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2194

## 8 REGISTRATION NUMBER(S)

29/13.1/0267

## 9 Date of first authorisation/renewal of the authorisation

November 1997

## 10 Date of revision of the text

17 December 2025