Patient Information Leaflet for Medicines for Human Use

SCHEDULING STATUS: S0

CETIDINE CONCENTRATE (Liquid)

Chlorhexidine gluconate

Cetrimide

Preservative

Isopropanol

Contains Tartrazine

Read all of this leaflet carefully because it contains important information for you.

CETIDINE CONCENTRATE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CETIDINE CONCENTRATE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CETIDINE CONCENTRATE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What CETIDINE CONCENTRATE is and what it is used for.

2. What you need to know before you use CETIDINE CONCENTRATE.

3. How to use CETIDINE CONCENTRATE.

4. Possible side effects.

5. How to store CETIDINE CONCENTRATE.

6. Contents of the pack and other information.

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1. What CETIDINE CONCENTRATE is and what it is used for

13.1 Antiseptics, Disinfectants and Cleansing agents

Chlorhexidine, combination-Pharmacotherapeutic group: Antiseptic and disinfectants,

ATC code: D08AC52

CETIDINE CONCENTRATE liquid has detergent and antiseptic cleansing properties. It is used for cleansing physically contaminated wounds and burns.

For external use only.

2. What you need to know before you use CETIDINE CONCENTRATE

Do not use CETIDINE CONCENTRATE Liquid:

- If you are hypersensitive (allergic) to cetrimide, chlorhexidine gluconate or any of the other ingredients of CETIDINE CONCENTRATE (listed in section 6),
- Near or in contact with the eyes, brain, meninges, or middle ear,
- In body cavities.

WARNINGS AND PRECAUTIONS

Special care should be taken with CETIDINE CONCENTRATE:

- Contains Tartrazine and may cause allergic reaction.
- Do not apply 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.
- 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.

- Brown stains may develop on fabric which comes in direct contact with CETIDINE CONCENTRATE solution. An oxidising bleach such as sodium perborate should be used in laundering.
- Organic matter and soap reduce the activity of CETIDINE CONCENTRATE

Other medicines and CETIDINE CONCENTRATE

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

No interaction studies have been performed.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

No studies have been established in pregnant or lactating women.

Driving and using machines

It is not always possible to predict to what extent CETIDINE CONCENTRATE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CETIDINE CONCENTRATE affects them.

3. HOW TO USE CETIDINE CONCENTRATE

Always use CETIDINE CONCENTRATE exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you. Check with your doctor or , pharmacist or nurse if you are not sure.

FOR EXTERNAL USE ONLY.

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.

If you use more CETIDINE CONCENTRATE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. POSSIBLE SIDE EFFECTS

CETIDINE CONCENTRATE can have side effects.

Not all side effects reported for CETIDINE CONCENTRATE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using

CETIDINE CONCENTRATE, please consult your doctor, pharmacist, or other health care provider for advice.

If any of the following happens, stop using CETIDINE CONCENTRATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity including anaphylactic shock (swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing.
- Ototoxicity.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CETIDINE CONCENTRATE. You may need urgent medical attention or hospitalization.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of CETIDINE CONCENTRATE.

5. HOW TO STORE CETIDINE CONCENTRATE

Store all medicines out of reach of children.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CETIDINE CONCENTRATE contains

The active substances are cetrimide and chlorhexidine gluconate.

Each 100 mL contains 15 % *w/v* cetrimide and 1,5 % *w/v* chlorhexidine gluconate.

The other ingredients are:

Isopropanol (Preservative)

Pine Oil

Purified Water

Yellow Tartrazine

Carmosine Red Dye

What CETIDINE CONCENTRATE looks like and contents of the pack

CETIDINE CONCENTRATE is a clear, orange liquid that foams when shaken with a pine odour. CETIDINE CONCENTRATE is packed a 5L HDPE bottle with a HDPE cap.

Holder of Certificate of Registration

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