BIOTAINE (liquid)

SCHEDULING STATUS:

S0

PROPRIETARY NAME (AND DOSAGE FORM):

BIOTAINE (Liquid)

COMPOSITION:

Each 100 ml Biotaine contains 5 g Chlorhexidine Gluconate equivalent to 25 ml Chlorhexidine Gluconate Solution B.P.

PHARMACOLOGICAL CLASSIFICATION:

13.1 Antiseptics, Disinfectants and Cleansing Agents.

PHARMACOLOGICAL ACTION:

Biotaine has cleansing and detergent properties. Chlorhexidine is active in vitro against a number of Gram negative and Gram positive vegetative bacteria, yeasts and dermatophyte fungi.

INDICATIONS:

Biotaine is an antimicrobial agent for general antiseptic purposes.

CONTRA-INDICATIONS:

Should not be used on the brain, meninges or middle ear. Skin sensitivity to Chlorhexidine. Do not use in body cavities.

WARNINGS:

For external use only.

DOSAGE AND DIRECTIONS FOR USE:

For external use only

Method of Preparation	Concentration of Chlorhexidine Gluconate required	Use
1ml made up to 100 ml with water (1 in 100)	1 in 2000 (0.05 %) Aqueous	Swabbing in obstetrics, gynaecology and urology. Disinfection of wounds and burns. Storage of sterile instruments
10ml with 15ml water made up to 100ml with 95 % alcohol (1 in 10)	1 in 200 (0.5 %) in 70 % alcohol	Pre-operative skin disinfection. Emergency disinfection of clean instruments (2 minutes immersion), containing cemented glass components.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Skin sensitivity to chlorhexidine and ototoxicity have been reported. For external use only. Keep away from eyes and ears. In case of contamination, wash with clean water, and if irritation continues, consult a doctor. Biotaine is incompatible with soap and other anionic agents.

KNOWN SYMPTOMS OF OVERDOSAGE AND ITS TREATMENT:

Accidental ingestion – empty stomach by aspiration and gastric lavage. Treatment is symptomatic and supportive.

IDENTIFICATION:

A light red solution having a faint medicinal odour.

PRESENTATION:

100 ml, 500 ml, 1 L, and 25 L plastic containers. 10 ml and 20 ml sachets.

STORAGE INSTRUCTIONS:

Store in airtight containers in a cool place (below 25° C). Cork closures must not be used. Keep out of reach of children.

REGISTRATION NUMBER:

S/13.1/158

NAME AND ADDRESS OF THE APPLICANT:

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