SCHEDULING STATUS

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PROPRIETORY NAME (AND DOSAGE FORM):

BIOTAINE IN ALCOHOL

(Liquid)

COMPOSITION:

Each 100 ml of Biotaine in Alcohol contains 0.5 % v/v (2.5 ml Chlorhexidine Gluconate Solution B.P in 70 % Alcohol Solvent), preserved in 0.4 % v/v Isopropyl Alcohol.

PHARMACOLOGICAL ACTION:

Biotaine in Alcohol has cleansing and detergent properties.

INDICATIONS:

Biotaine in Alcohol is used as a skin antiseptic.

CONTRA-INDICATIONS:

Not for injection. Should not be used on the brain, meninges or middle ear. Skin sensitivity to Chlorhexidine. Do not use in body cavities. Chlorhexidine preparations are contra-indicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or any other ingredients.

WARNINGS:

For external use only.

DOSAGE AND DIRECTIONS FOR USE:

For external use only. The product is used as follows:

Concentration of Chlorhexidine Gluconate	USE
1 in 200 (0.55 in 70 % alcohol). Use undiluted	As a skin antiseptic

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Prolonged skin contact with alcoholic solutions should be avoided. Allow to dry before proceeding. 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. Special precautions has to be taken when this product, which contains alcohol, is used where diathermy is indicated.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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

IDENTIFICATION:

A light red aqueous solution having an odour of alcohol.

PRESENTATION:

100 ml, 500 ml, 1 L and 25 L high density white polyethylene containers.

STORAGE INSTRUCTIONS:

Store in airtight containers in a cool place (below 25°C)

Cork closures must not be used by the patient or the hospital. Keep out of reach of children. Protect from light and heat. For external use only.

REGISTRATION NUMBER:

33/13.1/0526

NAME AND ADDRESS OF THE APPLICANT:

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