

Professional Information for Medicines for Human Use**SCHEDULING STATUS**

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1. NAME OF MEDICINE

BIOTAINÉ IN ALCOHOL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL of BIOTAINÉ IN ALCOHOL contains:

Chlorhexidine gluconate solution	0,5 % w/v
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Propyl alcohol	70 % v/v
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Preservative

Isopropyl Alcohol	0,4 % v/v
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For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid

BIOTAINÉ IN ALCOHOL is a light red, aqueous liquid having an odour of alcohol.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

BIOTAINÉ IN ALCOHOL is used as a skin antiseptic.

4.2 Posology and method of administration

For external use only.

The product is used as follows:

Concentration of Chlorhexidine Gluconate required	Use
0,5 % in 70 % alcohol Use undiluted	As a skin antiseptic.

4.3 Contraindications

- Not for injection
- Known hypersensitivity to Chlorhexidine and Propyl alcohol or any other ingredients listed in section 6.1 "List of excipients"
- BIOTAINÉ IN ALCOHOL should not be used on the brain, meninges or middle ear
- Do not use in body cavities.

4.4 Special warnings and precautions for use

For external use only.

Prolonged skin contact with alcoholic solutions should be avoided.

Only use enough product to cover the area indicated for disinfection.

Do not use excessive amounts which can lead to pooling. Allow area to dry before proceeding.

Prevent pooling of the product as prolonged skin contact with alcoholic solutions can cause chemical burns. Ensure the area underneath the patient is completely dry, with no BIOTAINÉ IN ALCOHOL present on linen/linen-savers.

Avoid contact with eyes and ears. In case of contamination of the eyes and ears, wash with fresh clean water, and if irritation continues, consult a doctor.

Do not use on open skin wounds, broken or damaged skin.

Use with care in newborn babies, especially those born prematurely. It may cause chemical skin burns on these patients.

Special precautions must be taken when this product, which contains alcohol, is used where diathermy is indicated.

Avoid contamination of food with this product.

Keep away from flames and sunlight.

4.5 Interaction with other medicines and other forms of interactions

Do not mix this product with other substances.

4.6 Fertility, pregnancy, and lactation

Studies on fertility, pregnancy and lactation have not been established.

4.7 Effects on ability to drive and use machines

No or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

System Organ Class	Frequency	Side effects
Ear and labyrinth disorders	<i>Frequency unknown</i>	Ototoxicity
Skin and subcutaneous tissue disorders	<i>Frequency unknown</i>	Skin sensitivity

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '**6.04 Adverse Drug Reactions Reporting Form**'. Found under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Accidental ingestion – empty stomach by aspiration and gastric lavage. Treatment is symptomatic and supportive. See section 4.8 “Undesirable effects”.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

13.1 Antiseptics, Disinfectants and Cleaning Agents

Pharmacotherapeutic group: Chlorhexidine, combinations

ATC code: D08AC52 Chlorhexidine combinations

Mechanism of action

BIOTAINÉ IN ALCOHOL has cleansing and detergent properties.

Chlorhexidine gluconate is a cationic biguanide. Its antimicrobial action is due to the disruption of the cell membrane and the precipitation of cell contents. It has a bactericidal or bacteriostatic action against a wide range of gram-positive and gram-negative bacteria. It is relatively ineffective against mycobacteria. It inhibits some viruses and is active against some fungi. It is inactive against bacterial spores.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alkonat L90

Carmoisine Red Dye H7110

Babyli perfume

Purified water.

6.2 Incompatibilities

BIOTAINÉ IN ALCOHOL is incompatible with soap and other anionic agents.

6.3 Shelf life

24 Months at or below 30 °C.

6.4 Special precautions for storage

Store in airtight containers, in a cool place, at or below 30 °C.

Cork closures must not be used by the patient or the hospital.

Keep away from open flames and sunlight.

6.5 Nature and contents of container

BIOTAINE IN ALCOHOL is packed in high density polyethylene (HDPE) 50 mL, 100 mL, 500 mL, 1 L and 5 L bottles closed with an HDPE cap. The 100 mL can also come with a mist spray cap.

Not all packs or pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

33/13.1/0526

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION.

28 May 2002

10. DATE OF REVISION OF THE TEXT

07 October 2024