



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

BIOTAINE IN ALCOHOL (Liquid)

Chlorhexidine gluconate solution	0,5 % w/v
Propyl alcohol	70 % v/v
Preservative	
Isopropyl Alcohol	0,4 % v/v

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

BIOTAINE IN ALCOHOL is available without a doctor's prescription. Nevertheless, you still need to use BIOTAINE IN ALCOHOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOTAINE IN ALCOHOL 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 BIOTAINE IN ALCOHOL is and what it is used for.
2. What you need to know before you use BIOTAINE IN ALCOHOL.
3. How to use BIOTAINE IN ALCOHOL.
4. Possible side effects.
5. How to store BIOTAINE IN ALCOHOL.
6. Contents of the pack and other information.

1. What Biotaine In Alcohol is and what it is used for

13.1 Antiseptics, Disinfectants and Cleaning Agents

Pharmacotherapeutic group: Chlorhexidine, combinations

ATC code: D08AC52 Chlorhexidine combinations

BIOTAINE IN ALCOHOL is used as a skin antiseptic.

2. What you need to know before you use BIOTAINE IN ALCOHOL

Do not use BIOTAINE IN ALCOHOL:

- For injection
- If you are hypersensitive to chlorhexidine gluconate, Propyl alcohol or any of the other ingredients of BIOTAINE IN ALCOHOL (listed in section 6)
- On the brain, meninges or middle ear
- In body cavities.

Warnings and precautions

For external use only.

Take special care with BIOTAINE IN ALCOHOL:

- Avoid prolonged skin contact with alcoholic solutions
- Do not use excessive amounts which can lead to pooling. Only use enough product to cover the area indicated for disinfection
- 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 BIOTAININE 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
- In newborn babies, especially those born prematurely. It may cause chemical skin burns on these patients
- When used where diathermy is indicated
- Avoid contamination of food with this product,
- Keep away from flames and sunlight

Other medicines and BIOTAININE IN ALCOHOL

Always tell your health care provider if you are using any other medicines (this includes all complementary or traditional medicines).

Do not mix this product with other substances.

Pregnancy, breastfeeding and fertility

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



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 advise before using this medicine.

Driving and using machines

BIOTAINE IN ALCOHOL has no or negligible influence on the ability to drive and use machines.

3. How to use BIOTAINE IN ALCOHOL

For external use only.

Always use BIOTAINE IN ALCOHOL exactly as described in this leaflet or as your doctor, pharmacist or other health care provider has told you. Check with your health care provider if you are not sure.

The product is used as follows:

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



If you take more BIOTAINÉ IN ALCOHOL than you should

If you accidentally ingest BIOTAINÉ IN ALCOHOL, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Empty stomach by aspiration and gastric lavage. Treatment is symptomatic and supportive.

4. Possible side effects

BIOTAINÉ IN ALCOHOL can have side effects.

Not all side effects reported for BIOTAINÉ IN ALCOHOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BIOTAINÉ IN ALCOHOL, please consult your healthcare provider for advice.

If any of the following happens, stop using BIOTAINÉ IN ALCOHOL and tell your doctor.

Frequency unknown:

- Ototoxicity (hearing or balance problems due to a medicine)
- Skin sensitivity.

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOTAINÉ IN ALCOHOL.

5. How to store BIOTAININE IN ALCOHOL

- Store in airtight containers in a cool place, at or below 30 °C
- Do not use cork closures
- Keep away from open flames and sunlight
- Store all medicines out of reach of children.

6. Contents of the pack and other information.

What BIOTAININE IN ALCOHOL contains

Each 100 mL of BIOTAININE IN ALCOHOL contains:

Chlorhexidine gluconate solution 0,5 % w/v

Propyl alcohol 70 % v/v

Preservative

Isopropyl Alcohol 0,4 % v/v

Other ingredients: Alkonat L90, Carmoisine Red Dye H7110, Babyli perfume, Purified water.

What BIOTAININE IN ALCOHOL looks like and contents of the pack

Light red, aqueous liquid having an odour of alcohol.

BIOTAININE 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.



Holder of Certificate of Registration

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