

ANNEX IIIB

Package leaflet: Information for the user

DERMOBACTER, solution for cutaneous application

Benzalkonium chloride / chlorhexidine digluconate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What DERMObACTER, solution for cutaneous application is and what it is used for
2. What you need to know before you use DERMObACTER, solution for cutaneous application
3. How to use DERMObACTER, solution for cutaneous application
4. Possible side effects
5. How to store DERMObACTER, solution for cutaneous application
6. Contents of the pack and other information

1. What DERMObACTER, solution for cutaneous application is and what it is used for

Pharmacotherapeutic group: ANTISEPTIC (D. dermatology) - ATC Code: D08AC52.

DERMOBACTER is used for cleansing or locally treating skin disorders and mucous membranes that are infected or at risk of infection.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use DERMObACTER, solution for cutaneous application

Do not use DERMObACTER, solution for cutaneous application:

- if you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6),
- for an application in the eyes or ears,
- if you need to disinfect medical or surgical equipment.

IF ANY DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and precautions

Talk to your doctor or pharmacist before using DERMObACTER, solution for cutaneous application.

Warnings

This medicine is for external use only.

The active substances may pass into the general circulation when used on a large surface, under occlusive dressing, on a damaged skin (burnt in particular), a skin of premature infant or neonate.

Use with care in newborn babies, especially those born prematurely. DERMOBACTER, solution for cutaneous application may cause chemical skin burns.

Precautions for use

Use properly and do not keep an opened bottle for a long time as a microbial contamination is possible once opened, especially if the bottle contains more than 250 mL.

IF ANY DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Children and adolescents

Not applicable.

Other medicines and DERMOBACTER, solution for cutaneous application

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine must not be used at the same time as other local antiseptics (risk of incompatibility or inefficacy). If soap is used first, it should be followed by careful rinsing.

DERMOBACTER, solution for cutaneous application with food and drink

Not applicable.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not apply the solution to the breasts during breast-feeding.

Driving and using machines

Not applicable.

DERMOBACTER, solution for cutaneous application contains

Not applicable.

3. How to use DERMOBACTER, solution for cutaneous application

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

The solution can be used pure or diluted once or twice a day.

- Pure use: application on the skin.
- Diluted use 1/10th: application on the external mucous membranes. The diluted solution must be prepared immediately before use and must not be stored.

Always rinse carefully after application.

Method of administration

CUTANEOUS ROUTE.

Do not swallow.

Duration of treatment

Follow the recommendations of your doctor or your pharmacist.

If you use more DERMOBACTER, solution for cutaneous application than you should

An excessive use may cause an aggravation of side effects. Moreover, a passage in blood circulation cannot be excluded in case of application on a large surface or under occlusive dressing.

If you forget to use DERMOBACTER, solution for cutaneous application

Not applicable.

If you stop using DERMOBACTER, solution for cutaneous application

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- dry skin and mucosal dryness sensation , which is attenuated by careful rinsing,
- slight skin irritation during the first applications,
- possibility of contact dermatitis,
- chemical burns in newborn babies (frequency unknown).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (ANSM - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DERMOBACTER, solution for cutaneous application

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Do not store above 25°C.

The diluted solution must be prepared immediately before use and must not be stored.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DERMOBACTER, solution for cutaneous application contains

- The active substances are:
 - Benzalkonium chloride solution0.985 g
 - Quantity corresponding to benzalkonium chloride0.500 g

 - Chlorhexidine digluconate solution1.065 g
 - Quantity corresponding to chlorhexidine digluconate0.200 g
- For 100 ml of solution for cutaneous application.

- The other ingredients are:
Betaine cocoalkyldimethyl 30% solution, poloxamer 188, hydroxyethylcellulose, citric acid monohydrate, sodium citrate, purified water.

What DERMOBACTER, solution for cutaneous application looks like and contents of the pack

This medicine is in the form of solution for cutaneous application.

Box of 1 bottle of 125 ml, 300 ml or 1000 ml.

Not all sizes may be marketed.

Marketing Authorisation Holder

LABORATOIRE INNOTECH INTERNATIONAL

22 AVENUE ARISTIDE BRIAND

94110 ARCUEIL

Manufacturer

INNOTHERA CHOUZY

RUE RENE CHANTEREAU, CHOUZY-SUR-CISSE

41150 VALLOIRE-SUR-CISSE

Name of the medicinal product in European Economic Area Member states

Not applicable.

This leaflet was last revised in February 2018.

Other sources of information

Detailed information on this medicine is available on the ANSM website (France).