

Package leaflet: Information for the user

Klorhexidin Fresenius Kabi 1 mg/ml, cutaneous solution

chlorhexidine diacetate

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, pharmacist or nurse have 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, pharmacist or nurse. 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 Klorhexidin Fresenius Kabi is and what it is used for
2. What you need to know before you use Klorhexidin Fresenius Kabi
3. How to use Klorhexidin Fresenius Kabi
4. Possible side effects
5. How to store Klorhexidin Fresenius Kabi
6. Contents of the pack and other information

1. What Klorhexidin Fresenius Kabi is and what it is used for

Klorhexidin Fresenius Kabi is indicated for disinfection of wounds, disinfection of mucus membranes in connection with child birth and disinfection of the urethral orifice before insertion of catheter.

Chlorhexidine kills or reduces the growth of different types of bacteria.

2. What you need to know before you use Klorhexidin Fresenius Kabi

Do not use Klorhexidin Fresenius Kabi

- if you are allergic to chlorhexidine diacetate or any of the other ingredients of this medicine (listed in section 6),
- in the ear,
- in the joints or tendon sheaths,
- in the brain or meninges.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Klorhexidin Fresenius Kabi.

Klorhexidin Fresenius Kabi must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly.

Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

The use of chlorhexidine on peritoneum may increase the formation of peritoneal adhesions.

Children

Use with care in newborn babies, especially those born prematurely. Klorhexidin Fresenius Kabi may cause chemical skin burns. Do not use excessive quantities and do not allow the solution to pool in skin folds or drip on sheets or other material in direct contact with the skin. Where occlusive dressings are to be applied to areas previously exposed to Klorhexidin Fresenius Kabi, care must be taken to ensure no excess product is present prior to application of the dressing.

Pregnancy and breast-feeding

No known risks.

Driving and using machines

No known effects.

3. How to use Klorhexidin Fresenius Kabi

Washing solution for external use. The effect may be reduced by soap, blood, puss or other organic material.

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.

4. Possible side effects

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

Rare (may affect up to 1 in 1,000 people): severe allergic reaction (hypersensitivity), skin irritation in form of contact dermatitis and urticaria.

Not known (frequency cannot be estimated from the available data): chemical burns in neonates. Corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Klorhexidin Fresenius Kabi

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

Do not use Klorhexidin Fresenius Kabi after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

No special precautions for storage. If a body warm solution is preferred, the bottle can be stored in a heating cabinet (+40°C) up to a week.

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. Further information

What Klorhexidin Fresenius Kabi contains

- The active substance is chlorhexidine diacetate
- The other ingredients are sodium acetate trihydrate, acetic acid and water for injections.

What Klorhexidin Fresenius Kabi looks like and contents of the pack

Plastic bottle (polyethylene): 125 ml, 250 ml, 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Market authorisation holder

[To be completed nationally]

Manufacturer

HP Halden Pharma AS

Svinesundsveien 80

1788 Halden

Norway

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