SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Klorhexidinsprit Fresenius Kabi 5 mg/ml cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 5 mg chlorhexidine digluconate.

Excipient with known effect:
563 mg ethanol per ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Disinfection of skin before injection, puncturing of skin, taking samples and surgery. Preoperative hand disinfection after hand washing with liquid soap.

4.2 Posology and method of administration

Method of administration

Preoperative hand disinfection: Disinfection of hands and forearms for at least 30 seconds, after prescribed hand washing.

Disinfection before perforation of the skin: Disinfect the skin surface and let the solution dry before perforation. Special attention should be given upon puncturing organs which are particularly sensitive to infection. Effect time is ½-2 minutes.

Preoperative skin disinfection: The operation area must be thoroughly disinfected for 2 minutes and the surface of the skin must dry before operation.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Chlorhexidine must not be used in the joints, tendon sheaths, brain, meninges or perforated eardrums, because it is neurotoxic.

4.4 Special warnings and special precautions for use

The use of chlorhexidine with alcohol on peritoneum may increase the formation of peritoneal adhesions (see section 5.3).

Chlorhexidine with alcohol is flammable. An area prepared with the product must be completely dry before the use of equipment that can cause sparks.

Klorhexidinsprit Fresenius Kabi must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Klorhexidinsprit Fresenius Kabi does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Klorhexidinsprit Fresenius Kabi comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

Paediatric population
The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life. See also section 4.4 'Excipients' below.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Klorhexidinsprit Fresenius Kabi, care must be taken to ensure no excess product is present prior to application of the dressing.

Excipients
This medicine contains 563 mg alcohol (ethanol) in each ml which is equivalent to 56.3 % (w/v). It may cause burning sensation on damaged skin. In neonates (pre-term and term newborn infants), high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

No known risks.

4.7 Effects on ability to drive and use machines

Klorhexidinsprit Fresenius Kabi has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

	Rare (≥1/10 000 to <1/1 000)	Not known (cannot be estimated from the available data)
Immune system disorders	Anaphylactic reaction	
Eye Disorders		Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*
Skin and subcutaneous tissue disorders	Contact dermatitis and urticaria	Chemical burns in neonates

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

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 via the national reporting system listed in Appendix V.

4.9 Overdose

No known risks.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptic and disinfecting agent, ATC code: D08A C02

Ethyl alcohol (70%) has an antimicrobial effect against gram-positive and gram-negative bacteria, tubercle bacteria and certain viruses (not hepatitis viruses). Combined with chlorhexidine the disinfection effect is increased and prolonged. Temporary as well as permanent skin flora is reduced and the antimicrobial effect lasts for several hours.
The effect of chlorhexidine may be reduced in the presence of soap, blood, pus and other organic matter. The solution is aseptically manufactured, skin friendly and the pH is 6,5-8,5.

5.2 Pharmacokinetic properties

Formal pharmacokinetic studies have not been performed.

5.3 Preclinical safety data

An animal study has shown increased intestinal adhesion formation after application of chlorhexidine on intestines in rat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life in unopened container: 2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Plastic bottle made of polyethylene:

125 ml
250 ml
1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 February 1985
Date of latest renewal: 01 January 2011

10. DATE OF REVISION OF THE TEXT

27-Sep-2024