SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Germolene Antiseptic Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol Ph. Eur.	1.2% w/w
Chlorhexidine digluconate solution B.P. to give Chlorhexidine digluconate	0.25% w/w

3. PHARMACEUTICAL FORM

Cream for topical administration.

4 CLINICAL PARTICULARS

4.1. Therapeutic Indications

The product will be recommended as an antiseptic (to help prevent secondary infection), local anaesthetic and emollient for minor cuts and grazes, minor burns and scalds and blisters, stings and insect bites, spots and other minor skin conditions, chapped or rough skin.

4.2. Posology and Method of Administration

All age groups:

Thoroughly clean the affected area of skin, apply the cream and rub gently. In the case of cuts or particularly tender areas, rubbing may be avoided by applying on a piece of white lint or gauze.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

Consult your doctor if symptoms persist.
Keep out of the reach of children
For external use only
Replace cap firmly after use

Rare but serious allergic reactions including anaphylaxis have been reported with use of chlorhexidine containing antiseptic products. If symptoms of a serious allergic reaction appear (e.g. wheezing or difficulty breathing, swelling of the face, hives that can quickly progress to more serious symptoms, severe rash, or shock), use must be discontinued immediately and doctor should be consulted.

Germolene Antiseptic Cream 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 Germolene Antiseptic Cream 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.
An ophthalmologist's advice should be sought.

The product should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents.

4.6. Pregnancy and Lactation

The product is not contraindicated during pregnancy and lactation. However, as with all medicines during pregnancy, caution should be exercised.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Skin disorders
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Eye disorders
Frequency not known: Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Repeated Topical Application
Frequently repeated topical application on the same site could theoretically lead to skin irritation. However, since the product is only intended for minor skin trauma, extensive exposure is unlikely.

Accidental or Deliberate Ingestion
The product would only be expected to be harmful if orally ingested in very large quantities. This is unlikely due to the unpleasant taste of the product. In such a case the primary concern would be the phenol intake which can cause nausea, vomiting, diarrhoea and headache.

Treatment
Gastric lavage with water and charcoal. Administration of demulcents such as egg white or milk and supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Phenol – antiseptic and local anaesthetic.
Chlorhexidine digluconate – antiseptic.

5.2. Pharmacokinetic Properties

The product has a local action with minimal risk of systemic effects.

5.3. Pre-clinical Safety Data

Preclinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cetostearyl alcohol
Light liquid paraffin
Polyoxyethylene - (21) - stearyl ether
Polyoxyethylene - (2) - stearyl ether
Dimethicone
Methyl salicylate
Sunset yellow (E110)
Ponceau 4R (E124)
Deionised water.

6.2. Incompatibilities

Chlorhexidine is incompatible with anionic agents.

6.3. Shelf life

Three years

6.4. Special precautions for storage

Do not store above 25^{o}C.

6.5. Nature and Contents of Container

a) Flexible aluminium tubes internally lacquered, fitted with an integral nozzle and a polypropylene cap. 5 g, 30 g, 33 g, 55 g or 120 g tubes are contained in boxboard carton.

b) Aluminium laminate tubes for 5g, 20g, 30g, 33g, 35g, 40g or 55g pack sizes consisting of 150µm polyethylene / 5µm polyacrylate outer layer, 30µm aluminium and an inner layer of 30µm polyacrylate / 60µm polyethylene, fitted with a HD polyethylene shoulder, an aluminium/EAA/surlyn tamper evident seal, with a polypropylene cap.

6.6. Instruction for use and handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8. MARKETING AUTHORISATION NUMBER

PL 00010/0263

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/05/2008

10 DATE OF REVISION OF THE TEXT

26/07/2024