SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Germolene Wound Care Cream

2. Qualitative and quantitative composition

Chlorhexidine Dihydrochloride 0.5 % w/w

A 10% overage is included.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

White cream for cutaneous use.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of minor skin trauma such as abrasions, cuts, scratches, burns, bites or stings, when there is a risk of bacterial infection. As a topical antiseptic in minor surgery.

4.2 Posology and method of administration

Posology:
For topical administration.

Adults:
Germolene Wound Care Cream should be applied once or several times daily, as required, to cleaned wounds or affected areas of the skin. Wounds may be treated in the usual manner, i.e. either by application of a dressing or by being left uncovered.

Elderly:
As for adults.

Children:
As for adults.

4.3 Contraindications

Known hypersensitivity to the product or its components, especially chlorhexidine.

Must not be applied to a perforated eardrum.

4.4 Special warnings and precautions for use

Avoid contact with the ears or mucous membranes.

Application over extensive skin areas should be avoided.

If infection persists or the condition worsens, consult a doctor.

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 Wound Care 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 Wound Care 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.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with soaps and other anionic compounds. As a precaution against the possibility of interference (antagonism or inactivation), Germolene Wound Care Cream should not be used concurrently with other antiseptics

4.6 Pregnancy and lactation

There is no evidence to suggest that the use of the cream should be restricted during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders and skin and subcutaneous tissue disorders
Allergic skin reactions such as dermatitis contact, dermatitis allergic, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters. Hypersensitivity, anaphylactic reaction, and anaphylactic shock with respective laboratory and clinical manifestations including asthma syndrome, mild to moderate reactions potentially affecting skin, respiratory tract, gastrointestinal tract, and cardiovascular system, including symptoms such as rash, urticaria, edema, pruritus, and cardio-respiratory distress.

Eye disorder:
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.go.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose
There is no danger with overdosage. Even when ingested accidentally by mouth, no special measures are necessary. In case of accidental conjunctival contact, which might cause some irritation, washing with water or saline would be sufficient.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and Disinfectants – Biguanides and Amidines

ATC Code: D08AC02

Chlorhexidine dihydrochloride is an antiseptic with bactericidal activity against gram-positive bacteria, notably sensitive strains of *Staphylococcus aureus,* the organisms most commonly implicated in skin infections. To a

somewhat lesser extent it is also active against gram-negative pathogens. Some *Pseudomonas* and *Proteus* species are resistant. It possesses only weak antifungal activity and displays some activity against lipophilic viruses. Chlorhexidine is most active at neutral or slightly alkaline pH. It is effective in the presence of blood and pus, although activity may be somewhat reduced by organic matter.

5.2. Pharmacokinetic properties

Absorption:
There is no evidence to suggest percutaneous absorption of chlorhexidine through intact adult skin. Low blood concentrations of chlorhexidine (1 µg/ml) were demonstrated in infants bathed in a 4% chlorhexidine gluconate detergent solution.

Distribution:
Because of its minimal degree of absorption through the skin, little is known about the distribution of chlorhexidine within organs or tissues. When administered orally (300mg) in healthy adults maximal plasma levels of 0.2 µg/ml can be detected after 30 minutes.

Elimination:
Chlorhexidine applied to the skin is virtually not absorbed. When administered orally, chlorhexidine is almost entirely excreted in the faeces.

5.3. Preclinical safety data

The acute oral toxicity of chlorhexidine in animals is low, with LD50 values in the range of 2-6 g/kg bw. No toxic effects were observed in rats receiving 0.05% chlorhexidine acetate for one year in drinking water. While chlorhexidine was mutagenic in Ames test, it was not mutagenic in mammalian genotoxicity assays. No evidence of the carcinogenicity of chlorhexidine was seen in long-term feeding studies. No evidence of impaired fertility or developmental toxicity has been reported for chlorhexidine. The potential for skin sensitisation is very low for chlorhexidine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dexpanthenol
DL Lactone
Cetyl alcohol
Stearyl alcohol
White soft paraffin
Liquid paraffin
Wool fat
Macrogol stearate

Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube inside lined with baked-on epoxy-phenolic lacquer coating.
Screw closure: 90g tube: HD polyethylene. 30g tube: polypropylene
Pack sizes: 90g, 30g

6.6 Special precautions for disposal

No special precautions necessary

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8. MARKETING AUTHORISATION NUMBER

PL 00010/0313

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/03/2006

10 DATE OF REVISION OF THE TEXT

26/07/2024