Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bepantiseptic First Aid Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol	1.20	% w/w
Chlorhexidine Digluconate Solution to give Chlorhexidine Digluconate	0.25	% w/w

Also contains cetostearyl alcohol 10% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A pink, viscous, homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of minor skin irritations.

4.2 Posology and method of administration

Apply as necessary after cleansing for up to 3 days.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If symptoms persist or the condition worsens, consult your 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.

4.5 Interaction with other medicinal products and other forms of interactions

Chlorhexidine is incompatible with anionic agents.

4.6 Fertility, pregnancy and lactation

Although use of this product is not contraindicated during pregnancy and lactation, 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

Spontaneous reports of hypersensitivity reactions (hypersensitivity, anaphylactic reaction, anaphylactic shock) have been made; frequency of these reactions cannot be estimated from the available data.
Rarely irritancy, rashes and other skin conditions may occur.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

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 gluconate: Antiseptic.

5.2 Pharmacokinetic properties

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

5.3 Preclinical 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
Dimeticone
Methyl salicylate
Sunset yellow (E110)
Ponceau 4R (E124)
Purified 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°C.

6.5 Nature and contents of container

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

Or

b)Aluminium laminate tubes for 5g, 30g, 33g 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/EEA/surlyn tamper evident seal, with a polypropylene cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1410/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd January 1987

Date of last renewal: 2nd January 2007

10 DATE OF REVISION OF THE TEXT

March 2021