

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cetrimide Antiseptic First Aid Cream
'Morrisons' Cetrimide Antiseptic First Aid Cream
Wilko Antiseptic Cream Cetrimide 0.5% w/w
Numark Antiseptic Cream Cetrimide 0.5% w/w
Superdrug Cetrimide Antiseptic 0.5% w/w Cream
Tesco Health Cetrimide Antiseptic 0.5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 0.50 % w/w.

Excipients of known effect:

Cetostearyl alcohol, 0.5% w/w

Ethyl parahydroxybenzoate E214, 0.032% w/w

Propyl parahydroxybenzoate E216, 0.016% w/w

Methyl parahydroxybenzoate E218, 0.124% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth opaque white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An antiseptic cream for chapped hands, minor skin abrasions and minor cuts.

4.2 Posology and method of administration

For all ages.

For general use, clean surrounding skin and apply cetrimide cream directly or on a piece of clean lint or gauze.

4.3 Contraindications

Hypersensitivity to cetrimide or any of the ingredients.

4.4 Special warnings and precautions for use

Use this medicine only on your skin.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)

E214, E216 and E218 may cause allergic reactions (possibly delayed).

Prolonged and repeated applications of cetrimide are inadvisable as hypersensitivity may occur.

Avoid contact with the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, Pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Hypersensitivity reactions may occasionally occur in certain individuals and present as localised contact dermatitis.

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

Overdosage with Cetrimide Cream B.P. is extremely unlikely. The ingestion of very large quantities of cetrimide and other quaternary ammonium compounds can cause nausea, vomiting, dyspnoea, cyanosis, CNS depression (sometimes preceded by excitement and convulsions), hypotension and coma. The fatal dose of quaternary ammonium compounds has been estimated to be 1 to 3 grams (equivalent to 200 – 600 grams of Cetrimide Cream B.P. 0.5% w/w).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08A J04 – Antiseptics & Disinfectants Quaternary Ammonium Compounds
Contains Cetrimide which is a topical disinfectant.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin

Cetostearyl Alcohol

Phenonip [containing Phenoxyethanol, Methyl parahydroxybenzoate (E218),

Ethyl parahydroxybenzoate (E214), Butyl parahydroxybenzoate, Iso butyl 4-hydroxybenzoate

Propyl parahydroxybenzoate (E216)]

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

As packaged for sale 48 months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

15g, 30g, 45g, 50g and 60g lacquered metal tubes with plastic cap.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Kent Pharmaceuticals Limited,
2nd Floor, Connect 38,
1 Dover Place, Ashford,
Kent, England, TN23 1FB

8 MARKETING AUTHORISATION NUMBER(S)

PL 08215/0192

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th July 2003

10 DATE OF REVISION OF THE TEXT

19/04/2022