

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CETAVLEX CREAM

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 0.5% w/w

3 PHARMACEUTICAL FORM

White Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

'Cetavlex' is an antiseptic cream for skin disorders such as minor wounds, minor burns and abrasions and napkin rash.

4.2 Posology and method of administration

Apply liberally to the affected area. In some cases it may be necessary to cover the wound or burn with a clean dressing.

4.3 Contraindications

'Cetavlex' is contra-indicated for patients who have previously shown a hypersensitivity reaction to cetrimide preparations.

4.4 Special warnings and precautions for use

If no improvement or there is aggravation, use should be discontinued and a physician consulted.

For topical application only. Keep out of the eyes and ears.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

See section 6.2.

4.6 Fertility, pregnancy and lactation

No special precautions are necessary.

4.7 Effects on ability to drive and use machines

It is unlikely that 'Cetavlex' cream would affect the ability to drive or operate machinery.

4.8 Undesirable effects

Side effects include allergic reactions and local irritation.

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

4.9 Overdose

The toxicity of 'Cetavlex' arises from the cetrimide content. It seems unlikely that systemic toxicity will occur from accidental ingestion of the cream. However, in the event of large quantities being swallowed, carry out gastric lavage with milk, raw egg, gelatin or mild soap. Do not induce vomiting.

Central paralysis cannot be countered by curare antagonists or CNS stimulants but sympathomimetic drugs have been given.

Mechanically assisted ventilation with oxygen may be necessary. Persistent convulsions may be controlled with cautious doses of diazepam or a short-acting barbiturate. Do not give alcohol in any form.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Studies with cetrimide have shown it to be active against a wide range of vegetative bacteria, both Gram positive and Gram negative, including *Staph. aureus* the commonest cause of infection in wounds and burns. Certain Gram negative bacteria, particularly strains of *Pseudomonas* and *Proteus* remain the least susceptible of the pathogenic bacteria to cetrimide, requiring a higher concentration than other species to produce an effective kill. There are no general pharmacological studies available on topically administered cetrimide preparations.

5.2 Pharmacokinetic properties

Cetrimide is strongly cationic in nature, binding strongly to skin and other

tissue, and thus absorption is negligible.

5.3 Preclinical safety data

Cetrimide is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial Methylated Spirits
Cetostearyl Alcohol
Liquid Paraffin
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Purified water

6.2 Incompatibilities

Cetrimide is incompatible with soap and other anionic agents.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store below 30°C.
Do not refrigerate.

6.5 Nature and contents of container

Internally lacquered aluminium tubes (50g).

6.6 Special precautions for disposal

Use undiluted

7 MARKETING AUTHORISATION HOLDER

Derma UK Ltd
The Toffee Factory
Lower Steenbergs Yard, Quayside
Ouseburn, Walker Rd
Newcastle upon Tyne
Tyne and Wear NE1 2DF
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 19876/0011

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

30 April 2004 / 13/08/2008

10 DATE OF REVISION OF THE TEXT

28/10/2019