PACKAGE INSERT TEMPLATE FOR CETRIMIDE

Brand or Product Name
[Product name] Cream
[Product name] Lotion

Name and Strength of Active Substance(s)
Cetrimide ….0.5 % w/w

Product Description

[Visual description of the appearance of the product (eg colour etc)]
eg :white and smooth cream

Pharmacodynamics

Cetrimide is a quaternary ammonium cationic disinfectant with bactericidal activity against gram-positive and some gram-negative organisms. Cetrimide is relatively ineffective against viruses.

Pharmacokinetics

No information available

Indication

For the treatment of cuts, abrasions, burns and wounds.

Recommended Dosage

Apply directly to the affected part 2 to 3 times daily. Suitable for adults, children, and the elderly.

Mode of Administration

Topical cream

Contraindications

Contra-indicated in patients with known hypersensitivity to cetrimide.

Warnings and Precautions

Prolonged and repeated applications of cetrimide to the skin may lead to hypersensitivity. Avoid contact with eyes. For external use only; not for use in body cavities.

Interactions with Other Medicaments

None known.

Statement on Usage During Pregnancy and Lactation

No information is available on the safety or use of the product in the above conditions.

Adverse Effects / Undesirable Effects

Skin irritation and occasionally sensitisation.

Overdose and Treatment

Overdose by the recommended route of administration is considered unlikely. Ingestion may cause nausea and vomiting. Toxic symptoms include dyspnoea and cyanosis, possibly leading to asphyxia. Depression of the central nervous system, hypotension and coma may also occur.

Treatment of poisoning is symptomatic. Demulcents and diluents may be given if necessary but emesis and lavage should be avoided. Activated charcoal may be considered if the patient presents within an hour of ingestion.

Storage Conditions
Store below 30°C, protect from light and moisture

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]