

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Vesagex Antiseptic Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide 1.0%w/w
For excipients, see 6.1

3. PHARMACEUTICAL FORM

A white opaque cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As an antiseptic cream for cuts and abrasions, minor skin disorders, dry and cracked skin, minor burns and nappy rash

4.2 Posology and method of administration

For external use only

For all ages and all listed indications; apply liberally as required

First aid: gently wash and dry the affected area, then apply the cream to soothe and help prevent infection.

Nappy rash: when changing the nappy, gently wash and dry the baby's skin and then apply the cream.

4.3 Contraindications

For cutaneous use only

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

4.4 Special warnings and precautions for use

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 orifices.

Antiseptic First Aid Cream contains the excipients cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

Label to state: FOR EXTERNAL USE ONLY.

Keep out of the reach and sight of children

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Skin irritation and occasionally sensitization.

Hypersensitivity may occur, presenting as localized contact dermatitis. Excessive dryness of the skin may occur in patients who become hypersensitive to cetrimide. Discontinue use (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.gov.uk/yellowcard.

4.9 Overdose

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 indigestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08A J04 – antiseptics and disinfectants, quaternary ammonium compounds

Cetrimide is a quaternary ammonium disinfectant with properties and uses typical of cationic surfactants. These surfactants dissociate in aqueous solution into a relatively large and complex cation, which is responsible for the surface activity, and a smaller

inactive cation. It has bactericidal activity against Gram-positive and, at higher concentrations, against some Gram-negative organisms. Cetrimide is relatively ineffective against viruses.

5.2 Pharmacokinetic properties

Vesagex Antiseptic Cream is intended for cutaneous use only

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Liquid paraffin
Cetostearyl alcohol
Glycerol
Verbena oil
Purified water

6.2 Incompatibilities

Not applicable, cutaneous preparation
Cetrimide is incompatible with soaps and other anionic surfactants, Bentonite, Iodine, Phenylmercuric Nitrate and Alkali Hydroxides.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

White plastic tubs	Pack size 500g
Aluminium tubes	Pack size 15g, 30g and 60g
Not all pack sizes may be marketed	

6.6 Special precautions for disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

Strides Pharma UK Ltd
Unit 4 Metro Centre
Tolpits Lane, Watford
Hertfordshire, WD18 9SS
Trading as: Co-pharma

8. MARKETING AUTHORISATION NUMBER(S)

PL 13606/0079

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 February 1999 / 14 July 2006

10. DATE OF REVISION OF THE TEXT

08/06/2017