

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Vesagex 1% w/w Antiseptic Cream.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Cetrimide 1.0% w/w.

Excipients: Contains chlorocresol and cetostearyl alcohol.

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Cream.

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 apply the cream.

#### 4.3 Contraindications

For topical use only.

Hypersensitivity to any of the ingredients.

#### 4.4 Special warnings and precautions for use

Keep out of the reach of children.

Not for use around the eyes or ears.

If symptoms persist, discontinue use and consult your doctor.

Contains chlorocresol – may cause allergic reactions.

Contains cetostearyl alcohol - may cause local skin reactions (eg contact dermatitis).

#### 4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

## 4.6 Fertility, pregnancy and lactation

None stated.

## 4.7 Effects on ability to drive and use machines

No or negligible influence.

## 4.8 Undesirable effects

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

## 4.9 Overdose

Treatment of poisoning is symptomatic. Demulcents may be given if necessary but emesis and lavage should be avoided.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

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. It has bactericidal activity against Gram-positive and, at higher concentrations, against some Gram-negative organisms.

## 5.2 Pharmacokinetic properties

Vesagex is intended for topical 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.

## 6.3 Shelf life

3 years.

## **6.4 Special precautions for storage**

Store below 25°C.

## **6.5 Nature and contents of container**

White plastic tubs – pack size 500g

Aluminium tubes – pack size 15g & 60g

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**

Strides Pharma UK Ltd

Unit 4 Metro Centre

Tolpits Lane

Watford

WD18 9SS

United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA 0894/003/001

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

Date of first authorization: 09 September 1991

Date of last renewal: 09 September 2006

## **10 DATE OF REVISION OF THE TEXT**

August 2017