# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Cymex Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | |
|---|---|
| Urea PhEur | 1.0% w/w |
| Cetrimide PhEur | 0.5% w/w |
| Dimeticone 350 PhEur | 9.0% w/w |
| Chlorocresol PhEur | 0.1% w/w |

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Emollient White Cream

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the application to cold sores and cracked lips.

### 4.2 Posology and method of administration

There are no special hazards associated with the use of cetrimide in specific patient groups. No special precautions or modified dosage requirements are, therefore, indicated for its use in infants, the elderly or during pregnancy or lactation. No hazardous drug interactions are considered likely.

Adults, elderly and children: apply sparingly every hour for the relief of cold sores and cracked lips.

Topical application.

### 4.3 Contraindications

Hypersensitivity to urea, cetrimide, dimeticone, chlorocresol or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

Cymex Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Keep out of the sight and reach of children.
For external use only.
If symptoms persist consult your doctor.

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

None known.

### 4.6 Pregnancy and lactation

Consult a doctor before use if pregnant or breast-feeding.

### 4.7 Effects on ability to drive and use machines

Not applicable.

### 4.8 Undesirable effects

None.

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

### 4.9 Overdose

Features
Symptoms are unlikely to arise after ingestion of this product. It is possible that nausea and vomiting or diarrhoea may occur.

Management
Gut decontamination or other specific management is unlikely to be required. Treat symptomatically. A small glass of milk or water may be helpful.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

ATC Code DO 2A X

Urea has keratolytic properties, Cetrimide is a quaternary ammonium disinfectant, Chlorocresol is a mild disinfectant while Dimeticone 350 acts as a water repellent.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

No particular remarks.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Deionised Water
Liquid paraffin BP
Cetosteryl Alcohol BP

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below 25°C.

### 6.5 Nature and contents of container

5 g White Aluminium tubes with Elongated nozzles and HDPE caps. Internally lacquered.

### 6.6 Special precautions for disposal

See 4.2 Posology and Method of Administration.

## 7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2539

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

13th December 2007

## 10 DATE OF REVISION OF THE TEXT

08/02/2022