

# **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, cetrимide, 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 Fertility, 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](http://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**

5g 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**

Dexcel<sup>®</sup>-Pharma Ltd.  
2nd Floor, Bourn,  
1 Manor House Drive  
Coventry, CV1 2FX,  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 14017/0309

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

13/12/2007

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

11/12/2025