Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cymex Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Cream
Smooth white cream with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the application to cold sores and cracked lips.

4.2 Posology and method of administration

Posology
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.

Method of administration
Topical application.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Keep out of the reach and sight 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

Topical urea is considered suitable for use by all the age groups and during pregnancy and lactation although few animal and reproduction studies have been conducted.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

No serious toxicity has been reported with the use of topically administered urea and it is considered to be a very safe substance. No long-term side effects have been found and no epidermal and dermal atrophy has been reported. It has, however, been reported to causing burning and irritation if applied to inflamed, broken or exudative skin eruptions.

No cases of sensitisation or photosensitisation have been reported under therapeutic conditions. In patch tests, no positive reactions were found in 500 individuals (66 with cutaneous disease) using 3% urea in a vanishing cream base but 7 (3.7%) out of 190 patients and 7 (9.9%) out of 79 patients showed positive reactions respectively in two studies with 10% urea-containing preparations. It was suggested that the positive patch test reactions were toxic reactions due to the hypertonicity and acidity of the cream.

Long-term experience has demonstrated an extremely low incidence of adverse reactions associated with the topical use of cetrimide. At the concentrations recommended for use on the body, cetrimide is generally very well tolerated, but irritant skin reactions can occasionally occur. Rare instances of hypersensitivity, usually developing after repeated administration, have been reported. Contact dermatitis to a preparation containing cetrimide and chlorhexidine has been reported. There have been very occasional reports of severe burn-like reactions to concentrated cetrimide solutions and necrosis has been reported following the use of pure cetrimide powder.

Sensitisation reactions may also occur following application of chlorocresol to the skin and hypersensitivity has occurred following systemic administration of injections containing chlorocresol as a preservative. Immediate and delayed allergic contact dermatitis has been reported with chlorocresol 1 and 5%. Systemic effects are similar to those of phenol.

Adverse events from the clinical use of silicones appear to be rare. No data are available to suggest any harmful effects in pregnancy and no special problems are anticipated in the elderly or children. No potentially hazardous interactions are known.

The adverse events reported above were obtained from pre-marketing spontaneous reports and as a result it is not possible to provide frequencies for the adverse reactions detailed in the table below.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
Necrosis
INMUNE SYSTEM DISORDERS
Hypersensitivity
NERVOUS SYSTEM DISORDERS
Burning sensation
SKIN AND SUBCUTANEOUS TISSUE DISORDERS
Dermatitis allergic
Dermatitis contact
Skin irritation

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

In the unlikely event of ingestion of large amounts of Cymex Cream, gastrointestinal irritation, such as nausea and vomiting, would be anticipated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other emollients and protective
ATC Code DO 2A X

Mechanism of action
The combination of urea, dimeticone, chlorocresol and cetrimide in a liquid paraffin/water base provides an emollient antiseptic preparation suitable for use on cold sores or cracked lips. Urea provides a moisturising action and dimeticone assists in providing a topical barrier to protect the sores and cracked lips against water-soluble irritants. The cream aids in moisturising, softening and protecting cracked lips and cold sores, once they have formed a crust. Cracking and chapping of cold sore vesicles may spread viral substrate, rendering the lesions more susceptible to bacterial infection, delaying healing and increasing discomfort. The antiseptics, chlorocresol and cetrimide, reduce the possibility of secondary bacterial infection developing.

Pharmacodynamic effects
Cymex cream contains 0.5%w/w cetrimide, a concentration commonly employed in creams for cleansing skin and wounds.

Chlorocresol is used in various preparations for disinfection of the skin and wounds. A concentration of 0.1% (as in Cymex cream) is used as a bacteriostat.

Creams, lotions and ointments containing dimeticone 10-30% are employed for the prevention of bedsores and napkin rash and to protect the skin against trauma due to incontinence or stoma discharge. The 9% w/w concentration of dimeticone in Cymex cream would, consequently, appear appropriate for use on cold sores and cracked lips.

Clinical efficacy and safety
No clinical studies are available on the combination of ingredients in Cymex cream but the product contains well established ingredients and provides a logical formulation for use on cold sores and cracked lips.

No reports of any adverse reactions to Cymex cream have been received by the company during its period of licensing. Over 1.25 million units of Cymex cream were sold during the period 1989 to 1992.

The properties of urea make it suitable for external use as it is a natural moisturiser and is well tolerated. It has been used in dermatological therapy from the beginning of the 1940's and has been used extensively in the treatment of dry skin both clinically and in cosmetic products.

Studies have shown preparations containing 10% urea suitable for increasing the water-binding capacity in the horny layer of diseased skin whereas those containing 2 or 5% urea were insufficient to reach the urea concentration necessary for normal human stratum corneum. For cosmetic purposes, the higher concentrations of urea were inappropriate and concentrations of 2-3% and below are considered more suitable. The 1% concentration of urea in Cymex cream should afford some moisturising activity.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Cetostearyl alcohol

Deionised 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 aluminium tube, internally lacquered, with an elongated nozzle and HDPE cap. 5g pack size.

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

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/112/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1997

Date of last renewal: 23 April 2007

10 DATE OF REVISION OF THE TEXT

September 2022