

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Urea 10% w/w Cream.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea 10% w/w cream contains Urea 10% w/w.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream

A smooth, unperfumed, non-greasy, off-white cream for topical administration.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the management of ichthyosis, xeroderma, hyperkeratosis and other chronic dry skin conditions.

### 4.2 Posology and method of administration

Urea 10% w/w Cream is applied topically. Wash affected areas well, rinse off all traces of soap, dry, and apply sparingly twice daily. Occlusive dressings may be used but are usually unnecessary because of the self-occlusive nature of the cream.

### 4.3 Contraindications

Known hypersensitivity to the product.

### 4.4 Special warnings and precautions for use

Avoid application to moist or broken skin.

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

Urea 10% w/w Cream may increase the penetration through the skin barrier of other topically applied medicaments.

### 4.6 Fertility, pregnancy and lactation

Animal reproduction studies have not been conducted with Urea 10% w/w Cream . Urea 10% w/w Cream should only be used if the anticipated benefits outweigh the risks.

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

Urea 10% w/w Cream does not interfere with the ability to drive or use machines.

### 4.8 Undesirable effects

May cause local irritations (including erythema, burning or pruritus) and oedema when applied to sensitive skin. If the condition is aggravated or there is no improvement, the doctor should be consulted.

## 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### **4.9 Overdose**

Topical applications of excessive amounts of Urea 10% w/w Cream might cause skin irritation but no other effects would be expected. Ingestion of a large amount of Urea 10% w/w Cream would be expected to result in gastrointestinal irritation (nausea and vomiting). Symptomatic and supportive care should be given. Liberal oral administration of milk or water may be helpful.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Urea acts as a hydrating and keratolytic agent.

#### **5.2 Pharmacokinetic properties**

Urea is primarily excreted in the urine. A small amount is also eliminated in sweat.

#### **5.3 Preclinical safety data**

In man, doses of up to 80g/day iv or 100g/day p.o urea are considered safe.

Whilst only very limited preclinical data is available, there is no evidence to suggest that urea would have teratogenic, carcinogenic or mutagenic potential in therapeutic use.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

The cream also contains:

White soft paraffin  
Maize starch  
Isopropyl myristate  
Glyceryl tribehenate  
Palmitic acid  
Sorbitan laurate  
Polyoxyethylene fatty glyceride

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf life**

Three years.

#### **6.4 Special precautions for storage**

Do not store above 30°C .

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

Urea 10% w/w Cream is available in tubes of 30 g and 100g.

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**

Alliance Pharma (Ireland) Limited  
United Drug Distributors, United Drug House  
Magna Business Park, Magna Drive  
Citywest  
Dublin 24  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA2325/008/001

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

Date of First Authorisation: 07 January 1975

Date of last Renewal: 07 January 2010

**10 DATE OF REVISION OF THE TEXT**

March 2019

CRN008KJQ