

## **1. NAME OF THE MEDICINAL PRODUCT**

Balneum Plus Cream

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active ingredient	Percentage (w/w)
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Lauromacrogols	3.0%
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Urea	5.0%
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## **3 PHARMACEUTICAL FORM**

Cream

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For the treatment of pruritus, eczema, dermatitis, and scaling skin conditions where an antipruritic and/ or hydrating effect is required. It may also be used for the continued treatment and follow-up treatment of these skin diseases.

### **4.2 Posology and method of administration**

Adults, the Elderly and Children: Balneum Plus Cream should be applied to each affected area twice a day. The duration of treatment depends on the clinical response.

### **4.3 Contraindications**

Patients with known hypersensitivity to any of the ingredients. It should not be used to treat acute erythroderma, acute inflammatory, oozing or infected skin lesions.

### **4.4 Special warnings and precautions for use**

Avoid contact to mucous membranes and eyes. Irritation (e.g. erythema, burning) may occur if applied to broken or inflamed skin.

Benzyl alcohol may cause allergic reactions and mild local irritation.

#### Children/Pediatric population:

Reports from the literature suggest that the use of urea-containing products in children may lead to a usually brief burning sensation on the skin.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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

Urea may increase the penetration through the skin barrier of other topically applied medicines (e.g. corticosteroids, dithranol and fluorouracil) when used at the same time

### **4.6 Fertility, Pregnancy and lactation**

For Balneum Plus Cream no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

There are no specific restrictions concerning its use during pregnancy, but it is not to be used on the breasts immediately prior to breast feeding during lactation.

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

None.

#### 4.8 Undesirable effects

The data given for frequency of adverse reactions is based on the following categories:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $1/1,000$ )

Very rare ( $< 1/10,000$ )

Not known (frequency based on available data not assessable)

Skin and subcutaneous tissue disorders:

Uncommon: skin burning sensation, erythema, pruritus, application site pustules

Not known: contact dermatitis, urticaria, rash, rash pustular.

##### 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### 4.9 Overdose

Not applicable.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Urea is a physiological product derived from human protein metabolism. It is found naturally in the skin and when applied topically it can increase the horny layer's capacity to retain water. Balneum Plus Cream has been shown to increase skin hydration and when used as recommended provides hydration for 24 hours. Patients with eczema and psoriasis have been shown to have decreased levels of urea in their skin. Urea is not allergenic and is well-tolerated at a concentration of 5%.

Lauromacrogols have the properties of a topical anaesthetic and have an antipruritic effect. The local tolerability of lauromacrogols is good.

Balneum Plus Cream has also been shown to increase the lipid content of the epidermis thus soothing and smoothing the skin.

After twice-daily application for 4 weeks to non-infected eczematous lesions, in addition to an improvement in the clinical condition, use of Balneum Plus Cream was associated with a significant reduction in total bacteria and Staph. aureus counts. A reduction in Staph. aureus count ( $p \leq 0.01$ ) was observed on eczematous skin from Day 1 (148 organisms/cm<sup>2</sup>) to Day 29 (11.8 organisms/cm<sup>2</sup>). However, no bactericidal or bacteriostatic effects have been tested for.

## **5.2 Pharmacokinetic properties**

Little urea is absorbed after topical application. It is mainly excreted in the urine, and to a lesser extent in perspiration.

There is no evidence of systemic availability of lauromacrogols after topical administration.

## **5.3 Preclinical safety data**

No specific studies have been performed with Balneum Plus Cream. Urea and lauromacrogols have been used therapeutically for many years in humans.

Information from animal studies are unlikely to provide any further relevant information.

# **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Dimethicone, phenyl dimeticone, liquid paraffin, cetylpalmitate, stearic palmitic acid, octyldodecanol, glycerol 85%, polysorbate, carbomer, trometamol, benzyl alcohol, purified water.

### **6.2 Incompatibilities**

Not applicable.

### **6.3- Shelf-life**

2 years

Shelf life after 1<sup>st</sup> opening: 6 months

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

Store below 25°C.

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

Aluminium tubes with double internal lacquer of epoxy phenol resin and closure made of polyethylene. Content: 10g, 35g, 50g, 75g and 100g.

Plastic pump dispensers. Content: 175g, 180g, 185g, 190g, 200g and 500g.

Plastic pump dispenser Airless HVDS 500 ml (Englass): Content: 500g

Plastic pump dispenser 525 ml Magic Star Dispenser Wiko: Content dispensed: 500 ml

### **6.6 Special precautions for disposal**

None stated.

**7     MARKETING AUTHORISATION HOLDER**

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Hamburg

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Germany

**8     MARKETING AUTHORISATION NUMBER(S)**

PL 33016/0010

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

31 July 1998

**10    DATE OF REVISION OF THE TEXT**

23/09/2019