

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Balneum Plus 82.95 % w/w and 15.00 % w/w bath additive

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of bath additive contains 829.5 mg of soya oil and 150 mg of lauromacrogols.

### Excipients with known effect:

1g of bath additive contains 8,5 mg of propylene glycol (E1520) and fragrance containing allergens.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Clear bath oil.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Balneum Plus is a bath oil the active ingredients of which have emollient and local anaesthetic properties and provide relief of pruritus. It is recommended for the treatment of dry skin conditions including those associated with dermatitis and eczema where severe pruritus is also experienced.

### 4.2 Posology and method of administration

#### Posology

Frequency and duration of the application should be adjusted according to the type and severity of the condition, adults should use the bath oil frequently (at least 3 times per week) whilst neonates and infants should be treated daily.

The following quantities are recommended: (If the skin requires considerable moisturising, 2-3 times these quantities can be used)

*Adults (including the elderly)*

For full bath (~100L) 20ml

For partial bath (~5L) 2.5ml

*Pediatric population (neonates and children)*

For bath (~25L) 5ml

For neonates and children daily application is recommended.

#### Method of administration

After shaking the bottle, Balneum Plus should be added to the bath water and mixed well.

A partial bath may be required when condition is localised e.g. the arm.

The temperature of the bath water should not exceed 36 °C as the regreasing effect is diminished at higher temperatures.

For the treatment of pruritus the temperature should be 32 °C or as low as can be tolerated.

The bath should not be longer than 20 minutes. In the case of infants and small children a bath of only a few minutes is mostly sufficient.

The duration of the therapy depends on the course of the disease. The instructions in the section 4.4 “Special warnings and precautions for use” should be taken into account.

Balneum Plus can also be used in the shower. In this case the preparation should first be evenly applied over the body without dilution. Subsequently the excess is removed under the shower. Soap, which would remove the desired oil film on the skin, should not be used.

Excessive rinsing with water after the bath counteracts the therapeutic action of Balneum Plus.

After a bath or shower the skin should only be lightly dabbed with a towel. Vigorous wiping and rubbing decreases the therapeutic effect.

### **4.3 Contraindications**

- Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.
- Hypersensitivity to peanut or soya.
- Fresh pustular forms of psoriasis (Psoriasis pustulosa).

In the case of

- major injuries to the skin and acute skin diseases of unknown cause,
- severe febrile and infectious diseases,
- cardiac insufficiency,
- hypertension,

all full baths — including those to which Balneum Plus has been added — should only be taken after consultation with the doctor.

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

As Balneum Plus deposits a film of oil over the skin, care should be taken to avoid slipping, especially in the bath or shower.

Contact with the eyes should be avoided and if it occurs the eyes should be washed out with copious amounts of clean water. Consult an ophthalmologist if irritation continues. Ingestion of the bath oil should be avoided.

This medicine contains 7.8 mg propylene glycol in each ml.

This medicine contains fragrance with allergens. These allergens (d-limonene, linalool) may cause allergic reactions.

The bathtub, shower and children's bathtub (if applicable) should be cleaned immediately after every bath using conventional household detergent and then rinsed out with hot water.

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 Interactions with other medicinal products and other forms of interaction**

The additional use of soaps or syndets neutralises the effect of Balneum Plus.

#### **4.6 Fertility, pregnancy and lactation**

No special precautions are recommended.

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

None known.

#### **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 (cannot be estimated from the available data)

#### Immune system disorders:

In very rare cases, soya oil may cause allergic reactions.

#### Skin and subcutaneous tissue disorders:

During the use of Balneum Plus there may be very rare cases of reddening, itching and burning.

The frequency in which rash and pustular rash may occur is not known.

#### 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**

In the event of oral ingestion the occurrence of symptoms is very unlikely owing to the low toxicity of the ingredients. No specific antidote or treatment is recommended.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Dermatologicals, Other emollients and protectives, ATC code: D02AX.

Lauromacrogols (polidocanol) is a local anaesthetic and has an antipruritic action. It is an effective infiltration and conduction anaesthetic.

### **5.2 Pharmacokinetic properties**

Polidocanol diffuses from skin and mucous membranes to the sensory nerves and therefore has an alleviating effect on the sensation of itch.

Although it has been suggested that local anaesthetics in general have little effect over the intact stratum corneum because of their inability to penetrate this barrier; this seems to apply only to the pure substance without a fatty base.

### **5.3 Preclinical safety data**

None relevant to the prescriber which are not mentioned elsewhere in this Summary of Product Characteristics.

### **6.1 List of excipients**

Propylene glycol (E 1520), ascorbyl palmitate, perfume oil (d-limonene, linalool), glyceryl stearate citrate.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

2 years

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

Do not store above 25° C.

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

Balneum Plus is supplied in high density polyethylene bottles in the following sizes: 200ml, 500ml and 2 x 500ml.

Not all pack sizes may be marketed.

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

Any unused medicinal product or waste material should be disposed of in accordance to local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Almirall Hermal GmbH  
Scholtzstrasse 3  
D-21465  
Reinbek  
Germany

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 33016/0009

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

10/07/2010

**10     DATE OF REVISION OF THE TEXT**

08/06/2022