

The format of this leaflet was set by the Ministry of Health and its content checked and approved

Summary of Product Characteristics

1. Name of the medicinal product

Balneum Plus, topical solution liquid.

Contains soya oil, polidocanol

2. Qualitative and quantitative composition

100 g of liquid bath additive contains:

soya oil (Ph.Eur.) 82.95 g

polidocanol (Ph. Eur.) 15.0 g

Excipients with known effect: propylene glycol, benzyl benzoate (aromatic ingredient).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid bath additive

Balneum Plus is a light yellow, cloudy, oily liquid.

4. Clinical particulars

4.1 Therapeutic indications

This medicinal product is a refatting medicinal oil bath with an itch-relieving (antipruritic) effect for preparing full, partial and shower baths.

It is used for the supportive treatment of all skin diseases associated with drying out.

4.2 Posology and method of administration

The preparation should be shaken before use!

For bathing, **Balneum Plus** is added to the bath water and thoroughly mixed until evenly distributed.

In order to correctly measure the required quantity, the inner section of the screw cap can be used as a measuring beaker.

For a full bath (approx. 150 l) 2 – 3 measuring beakers (30 – 45 ml) are used, for children's bath (approx. 25 l) 1/3 of a measuring beaker (5 ml) is used, and for a partial bath (5 l) approx. ¼ of a teaspoon (1 ml) of **Balneum Plus** is used.

The bath water temperature should not exceed 36 °C as the refatting effect slowly diminishes at higher temperatures. A lower bath water temperature (around 32 °C) is more favourable for fattening of the skin and better suited for treating pruritus.

The duration of the bath should be determined individually, but should not exceed 15 – 20 minutes. In the case of infants and small children a bath of only a few minutes is mostly sufficient.

For showering **Balneum Plus** is distributed undiluted on the moistened body and then showered off.

After bathing or showering the skin should only be lightly dabbed with a towel. Vigorous drying or rubbing reduces the therapeutic effect.

The frequency of the application of **Balneum Plus** depends on the type and extent of the symptoms and should be determined from individually. In general baths should be taken at intervals of 2 - 3 days; daily application is also possible if this is necessary.

4.3 Contraindications

Balneum Plus must not be used in the case of

- hypersensitivity to refined soya oil, soya, peanuts or any of the other ingredients of Balneum Hermal Plus stated in section 6.1.
- fresh pustular forms of psoriasis (Psoriasis pustulosa).

In the case of major skin injuries and acute skin diseases of unknown cause, severe febrile and infectious diseases, cardiac insufficiency and hypertension, all full baths, including those to which **Balneum Plus** has been added, should strictly only be taken after consultation with the doctor.

4.4 Special warnings and precautions for use

Undiluted **Balneum Plus** must not be allowed to come into contact with the eyes. In cases of accidental contact with the eyes rinse out immediately with copious amounts of cold water. If irritation continues, an ophthalmological examination is recommended.

Propylene glycol may cause skin irritations.

Benzyl benzoate contained in the perfume oil may cause slight irritation to the skin, eyes and mucous membranes.

There is an increased risk of slipping due to the oil film on the skin and the oil film in the bath or shower.

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

4.5 Interaction 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

There are no known restrictions with respect to use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Balneum Plus has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The frequencies of undesirable effects are indicated below:

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)

Skin and subcutaneous tissue disorders

Not known: flush, pruritus and burning, rash, pustular rash.

Very rarely, soya oil can cause allergic reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Ministry of Health according to the National Regulation by using an online form (<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il>) and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

There are no known adverse effects resulting from excessive oil concentrations in the bath water.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: dermatological balneotherapeutic preparations
ATC code: D11AB55

Balneum Plus results in a film of oil on the skin. This serves as a temporary protective layer until the lipid coat of the skin has been restored.

Balneum Plus decreases the dissolving of physiological moisturising factors (natural moisturizing factors: NMF) from the corneal layer and reduces the increased water evaporation present in cases of eczema - the so-called transepidermal water loss (TEWL).

Due to the addition of polidocanol, **Balneum Plus** also considerably relieves itching even at the low concentration in the bath water.

The use of **Balneum Plus** is medically indicated in the treatment of patients with skin which is low in grease, dry and intensely pruritic.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no proven cases of toxic symptoms resulting from baths with **Balneum Plus**.

6. Pharmaceutical particulars

6.1 List of excipients

Propylene glycol

Ascorbic palmitate
Perfume Oil DV 5171
Glycerin stearate citrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
Shelf life after first opening: 6 months.

6.4 Special precautions for storage

Store in a cool place, below 25°C.

6.5 Nature and contents of container

Pack sizes:

Bottles containing 100 ml
Bottles containing 200 ml
Bottles containing 500 ml

6.6 Special precautions for disposal

No special requirements.

7. Manufacturer

Almirall Hermal GmbH, Scholtzstrasse, 3 D-21465 Reinbek, Hamburg, Germany

8. Registration holder

Neopharm Ltd. 8 Hashiloach St, P.O. Box 7063, Petach Tiqva 49170001
Israel

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