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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, fragrance containing D limes and linalool.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid bath additive

Balneum Plus is a light yellow, opaque oily liquid.

4. Clinical particulars

4.1 Therapeutic indications

Refatting medical oil bath with antipruritic effect It is used for the supportive treatment of all skin diseases associated with drying out.

4.2 Posology and method of administration

Shake well before use!

If used in baths, add **Balneum Plus** to the bath water and mix well until distributed evenly. you can use the interior of the screw cap as a measuring cup to ensure that you add the recommended quantity of Balneum Plus:

Use 2 – 3 cups (30 – 45 ml) for a full bath (ca. 150 l);

Use a third of a cup (5 ml) for children's bathtub (ca. 25 l);

Use approx. quarter teaspoon (1 ml) for a soaking bath (5 l).

The bathwater temperature should not exceed 36 °C as the moisturising effect diminishes at higher temperatures. Lower bathwater temperature (around 32 °C) is more suitable for moisturising skin and for treating itches.

The bath time can be chosen individually but should not exceed 15 – 20 minutes. A treatment time of a few minutes is usually sufficient for infants and young children.

When used during a shower undiluted **Balneum Plus** is applied to wet skin and then rinsed off with water.

Gently pat the skin dry with a towel after bathing or showering. Rigorous towelling and rubbing will reduce the therapeutic effects.

How often **Balneum Plus** has to be used depends on the severity and type of symptoms and should be decided individually. In general, baths should be taken every 2 to 3 days; in some cases, daily use might be advisable.

4.3 Contraindications

Balneum Plus must not be used:

- in case of hypersensitivity to the active substances, peanut, soya, benzyl alcohol, D limes, linalool or any of the other ingredients of Balneum Plus listed in section 6.1.
- of recent cases of psoriasis (Psoriasis pustulosa).

In general, please consult with your doctor first before you take full baths -including when adding Balneum Plus- if you have large skin lesions and acute dermatological problems of unclear cause or if you suffer from severe febrile and infectious diseases, cardiac insufficiency and hypertension.

4.4 Special warnings and precautions for use

Undiluted **Balneum Plus** must not be allowed to come into contact with the eyes and mucous membranes.

In cases of accidental contact with eyes, rinse eyes immediately with plenty cold water. If irritation persists, seek medical attention from an ophthalmological.

The oil film on the skin and the interior of the bathtub or shower increases the risk of slipping. The bathtub, shower or children's bathtub must be cleaned using a standard household cleaner and rinsed with hot water immediately after each use.

This medication contains 8.5 mg propylene glycol per 1 g of product. Propylene glycol may cause skin irritations.

This medication contains fragrances based on D limes and linalool. D limes and linalool may cause allergic reactions.

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 will negate the effect of **Balneum Plus**.

4.6 Fertility, pregnancy and breastfeeding

There are no restrictions with use during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The frequencies of undesirable effects are 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 cannot be estimated from the available data)

System organ class	Frequency	Undesirable effects
Immune system disorders	Very rare	Allergic reactions
Skin and subcutaneous tissue disorder	Unknown	Redness, itching, burning sensation, skin rash accompanied by pustules.

D limes and linalool may 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 <https://sideeffects.health.gov.il/>

and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9 Overdose

No adverse effects caused by high oil concentrations in the bathwater are known.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatological balneotherapeutic
 ATC code: D11AB55

Balneum Plus forms an oil film on the skin. It acts as a temporary protective barrier until the natural so-called lipid layer of the skin has regenerated.

Balneum Plus reduces the amount of natural moisturising factors (NMF) from the horny layer of the skin when taking a bath and reduces the increased water evaporation of water associated with eczema - the so-called transepidermal water loss (TEWL).

Balneum Plus can also considerably ease itching through the added active ingredient 'polidocanol' even at a low dosage in the bathwater.

Balneum Plus is recommended for treatment of patients with a limited lipid layer on the skin or with dry skin prone to itching.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

So far there has been no evidence of toxic effects caused by baths after adding **Balneum Plus**.

6. Pharmaceutical particulars

6.1 List of excipients

Propylene glycol
Ascorbic palmitate
Perfume Oil Hands Care
Glycerin stearate citrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

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

9. Registration number:

135-49-25853

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