

This medicine is dispensed without a doctor's prescription

Balneum Plus

Medicated bath oil, solution for external use

Active ingredient composition in 100 grams of bath oil:

soya oil 82.95 g
polidocanol 15.00 g

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet.

Consult your pharmacist if you need further information. Consult your doctor if your signs of illness (symptoms) get worse or do not improve.

1. What is this medicine intended for?

Medical bath oil that restores skin moisture and helps alleviate itching.

Therapeutic group: skin emollients and refatting agents.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients, refined soybean oil, soya, peanuts, d-Limonene, linalool or any of the other ingredients in this medicine (see section 6).
- in cases of recent psoriasis (psoriasis pustulosa, psoriasis accompanied by pustules and sometimes fever and reduced general well-being).

In general, please consult your doctor before you take any full baths—including baths with Balneum Plus—if you have large skin lesions and acute dermatological problems for an unclear cause or if you suffer from severe febrile and infectious diseases, weak cardiac muscles (cardiac insufficiency) and high blood pressure.

Special warnings about using this medicine

Consult your doctor or pharmacist before using Balneum Plus.

Undiluted Balneum Plus must not come into contact with the eyes and mucous membranes. In case of accidental contact with eyes, rinse eyes immediately with plenty of cold water. If irritation persists, seek medical attention.

The oil film on the skin and the interior of bathtubs or shower floor increases the risk of slipping. Please ensure that you hold on to a secure handhold or stand stably at all times.

The bathtub, shower or children's bathtub must be cleaned using a standard household cleaner and rinsed with hot water after each use to prevent accumulation of bath oil residue.

Other medicines and Balneum Plus

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Using soaps or syndets (soap-free skin cleaners) at the same time will neutralize the effect of Balneum Plus.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant, or intend to become pregnant, consult your doctor or pharmacist before using this medication.

There are no restrictions known for use during pregnancy and breastfeeding.

Driving and using machines

No special precautions are required.

Important information about some of this medicine's ingredients

Balneum Plus contains propylene glycol and fragrances containing d-Limonene and linalool.

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

This medication contains fragrances based on d-Limonene and linalool. d-Limonene and linalool may cause allergic reactions.

3. How to use this medicine?

Always use this medication exactly as described in this leaflet or as directed by your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Directions for use:

Shake the product before use!

For use in the bath or shower.

For bathing, add Balneum Plus to the bath water and mix well until completely distributed. You can use the interior of the cap as a measuring cup to ensure that you add the recommended quantity of Balneum Plus.

Recommended dosage

For a full bath (about 150 litres)—add 30-45 ml Balneum Plus (2-3 caps)

For a child's bath (about 25 litres)—add 5 ml Balneum Plus (1/3 of a cap).

For a partial bath (about 5 liters)—use 1 ml Balneum Plus (1/4 teaspoon).

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

Bathing duration can be determined by individual preference but should not exceed 15-20 minutes.

Bathing duration of a few minutes is usually sufficient for infants and young children.

Balneum Plus can be used in the shower. If used in the shower, apply a suitable amount of undiluted Balneum Plus to wet skin and then rinse off.

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

How often you use Balneum Plus depends on the severity and type of symptoms and should be decided individually. Unless prescribed otherwise, baths with Balneum Plus should be taken every 2 to 3 days; in some cases, daily use may be advised.

Talk to your doctor if you think that the effect of Balneum Plus is too strong or too mild.

If you have used more Balneum Plus than you should

There are no known harmful effects of high concentrations of this oil in bathwater.

If you forget to use Balneum Plus

Do not use a double dose to make up for a missed dose. Continue using the medicine as prescribed by your doctor or as specified in the instructions in this leaflet.

If you stop using this medicine

You can stop using the product at any time. Stopping Balneum Plus is usually not harmful.

If a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Balneum Plus may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very rare side effects (may affect up to 1 in 10,000 people):

- allergic reactions.

Side effects of unknown frequency (frequency cannot be estimated based on available data):

- redness, itching, burning sensation, skin rash, skin rash accompanied by pustules (pustular rash).

- d-Limonene and linalool may cause allergic reactions.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

or email the registration holder's patient safety unit at: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C in a cool place. Use this medicine within 6 months of first opening.

6. Additional information

In addition to the active ingredients, this medicine also contains:

propylene glycol, ascorbyl palmitate, perfume oil hands care (contains d-Limonene, linalool), glyceryl stearate citrate.

What the medicine looks like and contents of the pack:

Balneum Plus is a turbid, light yellow, oily liquid. The product is packaged in pentagonal plastic bottles. Package sizes: 100 ml, 200 ml, 500 ml.

Not all pack sizes may be marketed.

Registration holder's name and address: Neopharm Ltd., 8 Hashiloach St., POB 7063, Petah Tikva, 49170001.

Manufacturer's name and address: Almirall Hermal GmbH, Scholtzstrasse 3, D-21465 Reinbek, Hamburg, Germany.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 135-49-25853

This leaflet was approved in February 2022, according to MOH guidelines.