

Package leaflet: Information for the user

Balneum Plus 82.95 % w/w and 15 % w/w Bath additive

Soya oil and lauromacrogols

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more advice. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Balneum Plus is and what it is used for
2. What you need to know before you use Balneum Plus
3. How to use Balneum Plus
4. Possible side effects
5. How to store Balneum Plus
6. Contents of the pack and other information

1. What Balneum Plus is and what it is used for

Balneum Plus is a bath additive that contains lauromacrogols and soya oil and is used for the treatment of dry skin disorders such as eczema and dermatitis where itching is a problem.

Balneum Plus rapidly relieves symptoms associated with dry, itchy skin whilst also cleansing and helping to protect the skin against further drying.

Soya oil is an emollient which soothes and softens dry skin by helping to replace lost oils. The oil forms tiny droplets in the water which leaves a thin film on your skin. This film helps to stop your skin drying out and so makes it feel soft.

The lauromacrogols are local anaesthetics for the relief of itching associated with eczema, dermatitis and problem dry skin.

2. What you need to know before you use Balneum Plus

Do not use Balneum Plus

- If you are allergic to soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from fresh pustular forms of Psoriasis (Psoriasis pustulosa).

All full baths – including those to which Balneum Plus has been added – should only be taken after consultation with your doctor in the following cases: major skin injuries, acute skin diseases of unknown cause, feverish and infectious diseases, heart failure and high blood pressure.

If the above applies to you, **do not** use this medicine and talk to your doctor.

Warnings and precautions

- Avoid getting Balneum Plus in your eyes, however, if this should occur, rinse immediately with clean water. If eye irritation remains please see your doctor.

- Undiluted Balneum Plus **should not** be swallowed. If this happens talk to your doctor or pharmacist immediately.
- Make sure the bath or shower water does **not** exceed 36°C, as this can make your skin condition worse.
- Take care **not** to slip in the bath or shower.
- Always clean the bath immediately after you have used Balneum Plus. To do this rinse thoroughly with hot water and then clean with a household cleaner.
- If your symptoms do not get better, go and see your doctor.

Do not 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.

Other medicines and Balneum Plus

There are no known interactions when using Balneum Plus with other medicines but please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not use soaps or syndets in addition to Balneum as this neutralises the effect of the product.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You may use Balneum Plus whilst you are pregnant.

Driving and using machines

Balneum Plus is not expected to have any effect on your ability to drive or use machines.

Balneum Plus contains propylene glycol and fragrance containing allergens

This medicine contains 7.8 mg propylene glycol in each ml.

This medicine contains fragrance with allergens. These allergens (benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamyl alcohol, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hydroxycitronellal, isoeugenol, d-limonene, linalool) may cause allergic reactions.

3. How to use Balneum Plus

Always use Balneum Plus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Balneum Plus is for external use by patients of all ages.
- Always **shake** the bottle before using Balneum Plus to make sure the ingredients are well mixed.
- Pour the appropriate amount of Balneum Plus liquid into the bath as the bath is filling (please see below for correct measurements), be careful the water is not too hot.
- Stay in the bath for at least 10 minutes but not longer than 20 minutes.
- **Do not** use soap since this will remove Balneum Plus from your skin and can also dry the skin.

- If only a small area of skin is affected, you may be able to bathe the affected area in a bowl or sink.

Measurements:

- For a full bath (Adults dose) – 1 capful (about 20 ml)
- For a child's or baby's bath – ¼ of a capful (about 5 ml)
- For a partial bath in a bowl or sink – 1/8 of a capful (about 2.5 ml)

If you have very dry skin, you can use two or three times the above amounts.

- Balneum Plus can also be used in the shower. In this case the liquid should be evenly applied over the body without dilution and then rinsed off under the shower.
- After bathing or showering gently pat dry with a towel. If you wipe or rub your skin too much the Balneum Plus will not work as well.
- Adults and children should bathe or shower with Balneum Plus at least 3 times a week or as often as required. Your doctor will advise you how often you should use Balneum Plus depending on how severe your skin condition is. For babies and infants a daily bath is recommended.

Duration of treatment

Your doctor will tell you for how long you need to use Balneum Plus.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Very rarely during use there may be cases of reddening, itching and burning.
- In very rare cases soya oil may cause allergic reactions.
- The frequency in which rash and with pustules accompanying rash may occur is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Balneum Plus

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

You should store Balneum Plus in its original pack.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Balneum Plus contains

- The active substances are soya oil 82.95% and lauromacrogols 15%.

Other ingredients

Propylene glycol (E 1520), ascorbyl palmitate, perfume oil DV 5171 (benzyl alcohol, benzyl benzoate, benzyl salicylate, cinnamyl alcohol, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hydroxycitronellal, isoeugenol, d-limonene, linalool), glyceryl stearate citrate.

What Balneum Plus looks like and contents of the pack

Balneum Plus is a clear bath oil.

Your medicinal product comes in 200 ml, 500 ml and 2 x 500 ml high density polyethylene bottles with a screw cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Almirall Hermal GmbH
Scholtzstraße 3, 21465 Reinbek, Germany

Manufacturer

Almirall Hermal GmbH
Scholtzstraße 3, 21465 Reinbek, Germany

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Ctra, Nacional II, Km 593
08740 Sant Andreu de la Barca
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OTHER INFORMATION

Self Help Measures

Eczema and dermatitis have many different causes and there are various self help measures you can adopt. If you want to find out more, you may find the following organisation helpful:

National Eczema Society,
11 Murray Street, London, NW1 9RE Telephone Number: 020 7281 3553