

PACKAGE LEAFLET: INFORMATION FOR THE USER

Balneum

Active substance: soya oil 84.75 %

Bath additive

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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT BALNEUM IS AND WHAT IT IS USED FOR

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

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

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BALNEUM

Do not use Balneum

- If you are allergic (hypersensitive) 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 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 in your eyes, however, if this should occur, rinse immediately with clean water.
If eye irritation remains please see your doctor.
- Undiluted Balneum **should not** be swallowed.
If this happens talk to your doctor or pharmacist immediately.
- Make sure water does not exceed 36°C, as this can make your skin condition worse.
- Take care **not** to slip in the bath.
- Always clean the bath immediately after you have used Balneum.
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.

Other medicines and Balneum

There are no known interactions when using Balneum 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 syndet 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 whilst you are pregnant.

Driving and using machines

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

Important information about some of the ingredients of Balneum

Due to its propylene glycol content this medicine may cause skin irritation.

Balneum contains soya oil: If you are allergic to peanut or soya, **do not** use this medicinal product.

The perfume contains benzylbenzoate which may be mildly irritant to the skin, eyes and mucous membranes.

It also contains butylated hydroxytoluene which may cause local skin irritation (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. HOW TO USE BALNEUM

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

- Balneum is for external use by patients of all ages.
- Pour the appropriate amount of Balneum 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.
- In the case of infants and small children a bath of only a few minutes is mostly sufficient.
- **Do not** use soap since this will remove Balneum 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.

- After bathing gently pat dry with a towel. If you wipe or rub your skin too much the Balneum will not work as well.
- Adults and children should bathe with Balneum 2 to 3 times a week or as often as required. Your doctor will advise you how often you should use Balneum depending on how severe your skin condition is. For babies and infants a daily bath is recommended.

Always clean the bath immediately after you have used Balneum. To do this, rinse the bath and equipment thoroughly with hot water and then clean with a household cleaner.

Duration of treatment

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

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

If you use more Balneum than you should

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Balneum 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

By reporting side effects you can also provide more information on the safety of this medicine.

5. HOW TO STORE BALNEUM

Keep out of the reach and sight of children.

Do not use Balneum 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 in its original pack.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Balneum contains

The active substance is soya oil 84,75 %.

The other ingredients are polyoxyethylene lauryl ether, oleic acid, diethanolamide, perfume oil, propylene glycol, butylated hydroxytoluene, ascorbyl palmitate and citric acid monohydrate.

What Balneum looks like and content of the pack

Balneum is an oily liquid.

Your medicinal product comes in either 20 ml, 95 ml, 100 ml, 150 ml, 200 ml, 225 ml, 250 ml, 300 ml, 500 ml, 2x500 ml, 600 ml or 1000 ml high density polyethylene bottles with a screw cap and also in 10 ml and 20 ml foil laminate sachets and 20 ml polyethylene/foil blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Almirall Hermal GmbH
Scholtzstraße 3, 21465 Reinbek, Germany
Tel.: +49 -40 727 04-0, Fax: +49 -40 722 92 96

Manufacturer

Almirall Hermal GmbH
Scholtzstrasse 3, 21465 Reinbek, Germany

Industrias Farmacéuticas Almirall, S.A.
Ctra. Nacional II, Km. 593, 08740 Sant Andreu de la Barca, Barcelona - Spain

This leaflet was last revised in: 02/2019

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, Hill House, Highgate Hill, London, N 19 5 NA.

Telephone Number: 020 7281 3553

