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.
- 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.
- 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

There are no known interactions when using Balneum with other medicines but please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including soaps or syndets in addition to Balneum as this neutralises the effect of the product.

Pregnancy and breast-feeding

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.

Balneum contains butyldihydroxytoluene and fragrance containing allergens
Butyldihydroxytoluene may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes. This medicine contains fragrance with allergens. These allergens (d-limonene, linalool) may cause allergic reactions.

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.

- For a full bath (Adults dose) – 1 capful (about 20 ml)
- For a child’s or baby’s bath – 1/2 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.

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.
- In case of side effects, 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 sight and reach 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%.

Other ingredients:

Polyoxyethylene laurel ether, oleic acid, diethanolamide, perfume oil (d-limonene, linalool), propylene glycol (E1520), butyldihydroxytoluene (E321), 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 20 ml, 95 ml, 100 ml, 150 ml, 200 ml, 225 ml, 250 ml, 300 ml, 500 ml, 1,000 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

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

Manufacturer

Farmaceutics Almirall, S.A.
Ctra. de Martorell 41-61, 08740 Sant Andreu de la Barca, Barcelona, Spain.

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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

Important Information

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 – 1/2 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.

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.

Driving and using machines

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, 1,000 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.

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