

PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SmPC) before prescribing.)

Balneum Plus

Soya oil 82.95 %w/w and Lauromacrogols 15.00% w/w bath additive

Active Ingredient: Soya oil 82.95 %w/w and Lauromacrogols 15.00% w/w

Indication: Balneum Plus is a bath oil and has emollient and local anaesthetic properties and provides relief of pruritus. It is recommended for the treatment of dry skin conditions including those associated with dermatitis and eczema where severe pruritus is also experienced.

Dosage and Administration:

The following quantities are recommended: (If the skin requires considerable moisturising, 2-3 times these quantities can be used)

Adults (including the elderly)

For full bath (~100L) 20ml
For partial bath (~5L) 2.5ml

Neonates and children

For bath (~25L) 5ml
For neonates and children daily application is recommended. The duration of the therapy depends on the course of the disease.

Consult SmPC and package leaflet for method of administration.

Contraindications, Warnings, etc:

Contraindications: Hypersensitivity to the active substances or to the excipient as listed in the SmPC section 6.1. Hypersensitivity to peanut and soya. Fresh pustular forms of psoriasis (Psoriasis pustulosa).

In the case of

- major injuries to the skin and acute skin diseases of unknown cause,
 - severe febrile and infectious diseases,
 - cardiac insufficiency,
 - hypertension,
- all full baths — including those to which Balneum Plus has been added — should only be taken after consultation with the doctor.

Precautions: As Balneum Plus deposits a film of oil over the skin, care should be taken to avoid slipping, especially in the bath or shower. Contact with the eyes should be avoided and if it occurs the eyes should be washed out with copious amounts of clean water. Consult an ophthalmologist if irritation continues. Ingestion of the bath oil should be avoided. Propylene glycol may cause skin irritations. Benzyl benzoate (part of perfume) may be mildly irritant to the skin, eyes and mucous membranes. The bathtub,

shower and children's bathtub (if applicable) should be cleaned immediately after every bath using conventional household detergent and then rinsed out with hot water.

Interactions: The additional use of soaps or syndets neutralises the effect of Balneum Plus bath oil.

Fertility Pregnancy and lactation: No special precautions are recommended.

Ability to drive and use machines: None known.

Adverse Reactions: The data given for frequency of adverse reactions is 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 based on available data not assessable).

Skin and subcutaneous tissue disorders: During the use of Balneum Plus there may be very rare cases of reddening, itching and burning. The frequency in which rash and pustular rash may occur is not known.

Immune system disorders: In very rare cases, soya oil may cause allergic reactions.

Legal Category: GSL

Marketing Authorisation Number(s): PL 33016/0009

NHS Cost: 500 ml - £6.66

Marketing Authorisation Holder:

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall Ltd.