

PRESCRIBING INFORMATION

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

Balneum

Soya oil 84.75% w/w bath additive

Active Ingredient: Soya oil 84.75% w/w

Indication: A bath oil for dry skin conditions including those associated with dermatitis and eczema.

Dosage and Administration: The bath oil should be added to bath water and thoroughly mixed until evenly distributed

For full bath (approx. 100 litres)	20ml (1 measure)
For child's bath (approx. 25 litres)	5ml (1/4 measure)
For partial bath (approx. 5 litres)	2.5ml (1/8 measure)

In particularly dry skin, 2-3 times the above quantities can be used. Generally, 2-3 baths should be taken weekly. For babies and infants a daily bath is recommended.

Consult SmPC and package leaflet for full 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 cases of major injury to the skin, acute skin diseases of unknown cause, severe febrile and infectious diseases, cardiac insufficiency and hypertension; full baths should only be taken after consultation with a doctor.

Precautions: Do not apply in the area of the eyes. In cases of accidental contact with the eyes rinse out immediately with copious amounts of cold water. Consult an ophthalmologist if irritation continues. Butyl hydroxytoluene may cause local skin irritations (e.g. contact dermatitis), irritations of the eyes and mucous membranes. Propylene glycol can cause skin irritations.

Benzyl benzoate contained in the perfume oil may cause light irritations of the skin, eyes and mucous membranes. There is an increased risk of slipping due to the oil film on the skin and the oil film in the bath or shower. 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 bath oil.

Fertility Pregnancy and lactation: There are no known restrictions with respect to use during pregnancy and the lactation period.

Ability to drive and use machines: Not applicable.

Adverse Reactions: During the use of Balneum bath oil there may be very rare cases of reddening, itching and burning. Soya oil may cause allergic reactions in very rare cases (<1/10,000).

Legal Category: GSL

Marketing Authorisation Number(s): PL 33016/0008

NHS Cost: 200 ml - £2.48, 500 ml - £5.38, 2x 500 ml - £10.39 (excluding VAT)

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.