

PRESCRIBING INFORMATION

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

Balneum Plus Cream

lauromacrogols 3.0 % w/w and urea 5.0 % w/w

Active Ingredient: lauromacrogols 3.0 % w/w and urea 5.0 % w/w.

Indication: For the treatment of pruritus, eczema, dermatitis and scaling skin conditions where an antipruritic and/or hydrating effect is required. It may also be used for the continued treatment and follow-up treatment of these skin diseases.

Dosage and Administration: Adults, the elderly and children: Apply to each affected area twice a day. The duration of treatment depends on the clinical response. For external use only.

Contraindications, Warnings, etc:

Contraindications: Patients with known hypersensitivity to any of the ingredients. It should not be used to treat acute erythroderma, acute inflammatory, oozing or infected skin lesions.

Warnings & Precautions: Avoid contact to mucous membranes and eyes. May cause irritation if applied to broken or inflamed skin.

Literature reports suggest that the use of urea-containing products in children may lead to a usually brief burning sensation on the skin.

Interactions: Urea may increase the penetration through the skin of other topically applied medicines (e.g. corticosteroids, dithranol and fluorouracil) when used at the same time. **Fertility, Pregnancy and lactation:** No clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. There are no specific restrictions concerning its use during pregnancy, but it is not to be used on the breasts immediately prior to breast feeding during lactation. **Effects on ability to drive and use machines:** None.

Undesirable Effects: *These are ranked under heading of frequency using the following convention: 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 ($< 1/10,000$).*

Uncommon: skin burning sensation, erythema, pruritus, application site pustules. *Consult SmPC in relation to other adverse reactions.*

Legal Category: GSL

Marketing Authorisation Number(s): PL 33016/0010

NHS Cost: (excluding VAT)

Tube containing 100g - £3.29

Pump pack containing 500g - £14.99

Marketing Authorisation Holder:

Almirall Hermal GmbH

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21465 Reinbek

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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.