

**NAME OF THE CLASS I MEDICAL DEVICE:**

**Balneum Cream**

**Ingredients:**

Urea 5 %, Ceramide NP, Aqua, Glycine Soya Oil, Propylene Glycol, Cetearyl Alcohol, Liquid Paraffin, Isohexadecane, Sodium Lactate, Lactic Acid, PEG-20 Stearate, Polysorbate 60, Squalane, Stearic Acid, Disodium EDTA, Lecithin, Tocopherol, Ascorbyl Palmitate, Hydrogenated Palm Glycerides Citrate.

Balneum Cream is free of fragrances, colourants and preservatives.

**Pharmaceutical form:**

White cream.

**Indications:**

Balneum Cream is formulated to protect the skin, to maintain skin moisture and to restore the impaired skin barrier in conditions giving rise to dry skin.

It contains urea, ceramide NP and physiological lipids. Urea is known to increase the skins ability to retain water and maintain skin hydration. Ceramide NP is known to help restore the barrier function of skin.

Balneum Cream is designed for daily use to relieve dry and very dry skin conditions including eczema, psoriasis and other dermatological conditions.

**Method of administration:**

Using clean hands, apply the cream to the skin once or twice daily.

**Contraindications:**

Patients with known hypersensitivity to any of the ingredients, soya or peanut.

**Warnings and precautions:**

For topical use only. Do not use on broken or inflamed skin. Caution should be exercised with concomitant treatment with other medicated topical products. If the condition becomes worse or if patients experience side effects/adverse incidents, discontinue treatment with Balneum Cream and seek medical advice.

**Adverse incidents:**

Although very few adverse incidents have been reported, the most frequent are local skin reactions.

**Special precautions for storage:**

Do not store above 25°C. Use within 6 months of first opening

**Pack sizes:**

Available in 50g (£2.85) and 500g (£9.97) pump dispensers.

**CE marking held by:**

Almirall Hermal GmbH, Scholtzstraße 3, 21465 Reinbek, Germany

**Distributed in the UK by:**

Almirall Ltd, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK.  
Tel: 0800 0087 399.

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**Adverse incidents should be reported. Online reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Almirall Ltd.**