

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BALMOSA CREAM

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Menthol BP	2.0%
	w/w
Camphor BP	4.0%
	w/w
Methyl Salicylate Ph.Eur.	4.0%
	w/w
Capsicum Oleoresin BPC	0.035%
	w/w

3 PHARMACEUTICAL FORM

Cream for cutaneous use

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Analgesic/rubefacient cream for the symptomatic relief of muscular rheumatism, fibrositis, lumbago, sciatica and unbroken chilblains.

4.2 Posology and method of administration

Adults and the elderly:

Apply topically. Massage gently into the affected area as required. Wash hands immediately after use.

Children under 12 years:

Not generally recommended.

4.3 Contraindications

Hypersensitivity to aspirin, other non-steroidal anti-inflammatory drugs, or any of the ingredients listed.

4.4 Special warnings and precautions for use

For external use only.

If skin sensitivity reactions occur, discontinue use. Do not apply to inflamed or broken skin. Avoid contact with the eye and mucous membranes. Do not apply to the nostrils of infants. Do not use with occlusive dressings.

After use avoid exposing the affected area to excessive sunlight.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

With all salicylates there is animal evidence of teratogenicity. Use should be avoided during pregnancy and breast feeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin sensitivity reactions are possible although rare. Topical application of large amounts of Balmosa Cream may result in systemic effects, including hypersensitivity and worsening of asthma.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdosage is extremely unlikely from topical use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Capsicum oleoresin is a rubefacient. Camphor exhibits counter-irritant and weak local anaesthetic activity. Menthol and methyl salicylate impart analgesic properties to the formulation.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylcellulose
White soft paraffin
Emulsifying wax
Liquid paraffin
Lanolin (anhydrous)
Phenonip
Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with a polyethylene cap containing 20g or 40g of the product.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Special Concept Development (UK) Limited T/A Rx Farma
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Watford, Hertfordshire,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 36722/0233

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

18 March 1983 / 22 May 1998

10 DATE OF REVISION OF THE TEXT

29/05/2025