IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1443/001/001
Case No: 2043305

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0100/015/001.

Galen Consumer Ltd.

212-220 Addington Road, **Selsdon**, **South Croydon**, **Surrey CR2 8LD**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Balmosa Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **23/11/2007** until **31/03/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Balmosa Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Menthol, racemic	2.0	% w/w
Camphor, racemic	4.0	% w/w
Methyl Salicylate	4.0	% w/w
Capsicum Oleoresin	0.035	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
Smooth homogeneous off-white cream with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical management of the symptoms of musculofibroarticular disorders such as rheumatism, fibrositis, lumbago, sciatica and unbroken chilblains.

4.2 Posology and method of administration

Gently rub into the painful area and keep covered, if possible.

4.3 Contraindications

Patients with a history of hypersensitivity to any of the active substances or excipients.

4.4 Special warnings and precautions for use

Skin sensitivity reactions are possible, although rare in occurrence.
Contact with eyes and all mucous membranes should be avoided and the hands should be washed thoroughly after applying the cream. Use should be discontinued if any evidence of irritation appears. Apply only to unbroken skin.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

As with all salicylates animal evidence of teratogenicity cautions use in pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin sensitivity reactions are possible although rare.

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
Wool fat
Phenonip containing:
Phenoxyethanol
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Purified water

6.2 Incompatibilities

Not applicable.

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

Internally lacquered aluminium tube with polyethylene cap containing 20g or 40g of cream.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GALEN CONSUMER LTD
212-220
Addington Road
Selsdon
South Croydon
Surrey
CR2 8LD
UK

8 MARKETING AUTHORISATION NUMBER

PA 1443/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

November 2007