

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Radian B Muscle Rub Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredients</u>	<u>% w/w</u>
Levomenthol	2.54
Total camphor as	1.43
Racemic camphor	1.41
Camphor Oil, White	0.32
Methyl salicylate	0.42
Capsicum oleoresin	0.005

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth, homogenous off-white cream with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of aches and pains including, muscular stiffness, bruising, sprains and fibrositis.

4.2 Posology and method of administration

For external application.

Adults and Children over 6 years.

Apply to the affected parts and slowly massage well into the skin. For muscular strains and stiffness it is best used after a hot bath.

Children under 6 years:

Not recommended.

Elderly:

The adult dose is appropriate.

4.3 Contraindications

Not to be used on children under 6 years old.

Do not apply to skin abrasions.

Do not apply to irritated skin.

4.4 Special warnings and precautions for use

Keep away from eyes and sensitive areas. If symptoms persist, consult a doctor. Use sparingly on tender skin and do not cover immediately after application. If an adverse reaction occurs, discontinue use immediately.

4.5 Interaction with other medicinal products and other forms of interaction

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin.

4.6 Pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy. Use in pregnancy only when there is no safer alternative. Use in lactation is acceptable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Known side effects of menthol – contact dermatitis or eczema, hypersensitivity reactions characterised by urticaria, flushing and headache.

4.9 Overdose

When used externally as directed overdose is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Radian B Muscle Rub is a smooth, off-white cream which incorporates menthol, camphor, methyl salicylate, capsaicin and white camphor oil as active ingredients and glycerol as emollient.

Menthol relieves itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect. Camphor acts as a rubefacient and mild analgesic and is employed as a counter-irritant. Methyl salicylate has the action of the salicylates. It is readily absorbed through the skin and has counter-irritant properties. Capsaicin has counter-irritant properties and white camphor oil is a rubefacient and mild counter-irritant.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Argobase S1 (containing lanolin, lanolin alcohols, cetostearyl alcohol and liquid paraffin)

Emulsifying Wax

White Petroleum Jelly

2, 4-Dichlorobenzylalcohol
Imidurea
Industrial Methylated Spirit
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube and plastic cap available in pack sizes of 15g, 25g, 40g or 100g or white plastic screw cap jar available in a pack size of 650g.

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

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8 MARKETING AUTHORISATION NUMBER

PA 506/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

August 2004