Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Radian B Muscle Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	% w/v
Levomenthol	1.40
Racemic camphor	0.60
Ammonium salicylate	1.00
Methyl salicylate	0.60

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution
A straw-coloured clear liquid with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For symptomatic relief of rheumatic and muscular pain, fibrositis, sciatica, lumbago, sprained ligaments, bruises, stiffness, strains, tennis elbow, golf shoulder and unbroken chilblains.

4.2 Posology and method of administration

Adults and Children over 12 years:

Sprinkle liberally onto the affected area and massage. Apply to the affected area 2 to 3 times a day.

4.3 Contraindications

1. Hypersensitivity to any of the ingredients.
2. Use in pregnancy or lactation.
3. Use in children under 12 years.
4. This product should not be applied to irritated or broken skin. If irritation develops, use of the product should be discontinued.

4.4 Special warnings and precautions for use

Hands should be thoroughly washed after use of this product and care should be exercised to avoid contact with the eyes and mucous membranes.
If you are on other medication, consult your doctor before use.
If pain persists or redness develops, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

When used concurrently with oral anti-coagulants, the agent will necessitate a lowering of their dosage and a careful monitoring of the coagulation system.

4.6 Pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy. Therefore, as with all medicines, use during pregnancy is not recommended unless directed by a doctor. Use in lactation is not recommended.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

As with other products of this type, occasionally people experience an adverse reaction. If this does occur, discontinue use immediately, and consult your doctor if symptoms persist. Known side effects of menthol-contact dermatitis or eczema, hypersensitivity reactions characterised by urticaria, flushing and headache.

4.9 Overdose

When used as directed overdose is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The Radian B product contains salicylate ions which have analgesic properties. Methyl and ethyl salicylate are readily absorbed through the skin and have counter-irritant properties. Menthol relives itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect. Camphor acts as a rubefacient and is employed as a counter-irritant.

5.2 Pharmacokinetic properties

The active ingredients are well known documented pharmacopoeial ingredients. The extent of percutaneous absorption in human volunteers of (^{14}C) acetyl salicylic acid from Radian B was studied and estimated by measurement of blood and urinary concentrations of radio activity.

Significant absorption though the skin was indicated by the excretion of almost 10% of the applied radio activity in the urine within 5 days with approximately 5.5% in the first 24 hours.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial methylated spirit
Glycerol
Citronella Oil

Ammonia
Water (purified)

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

High density polyethylene bottles with a urea formaldehyde cap containing a polyvinyldichloride coated pulpboard liner (30, 125 and 250 ml).

Glass bottles containing 50, 100 or 200 ml.

Silver HDPE bottle with silver coloured black urea cap and wad and LDPE insert. Pack sizes 125 and 250ml oval bottle.

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 506/17/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23 January 2003

10 DATE OF REVISION OF THE TEXT

August 2004