Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Radian B Pain Relief Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active components	%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 Spray, Solution
A container fitted with a pump dispenser, containing a clear almost colourless liquid with a slight yellow tinge and characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the 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 only:

Aerosol spray can

Spray in 2 or 3 short firm bursts onto the affected area, followed by a second application after 10-15 minutes.

Pump action spray

Spray as required on the affected area followed by a second application after 10-15 minutes.

Aerosol spray can and pump action spray

Smooth in or massage if preferred. If necessary, repeat application up to three times daily, reducing to morning and evening when acute symptoms subside. When convenient, use after a warm bath.

Children under 12:

Not recommended.

Elderly:

The adult dose is appropriate.

4.3 Contraindications

Not to be used on children under 12 years old. Do not apply to skin abrasions. Do not apply to irritated skin. Not to be used by persons who are sensitive to any of the ingredients.
Pregnancy and lactation.

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

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

4.6 Pregnancy and lactation

Use of the product during pregnancy and 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

No special precautions for storage.

6.5 Nature and contents of container

A HDPE bottle fitted with a pump action spray containing 100 ml, 120 ml or 140 ml.

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 506/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 9 January 2003

10 DATE OF REVISION OF THE TEXT

August 2004