Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ralgex Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycol monosalicylate	4.80 % w/v
Ethyl salicylate	4.80 % w/v
Methyl salicylate	0.96 % w/v
Methyl nicotinate	1.60 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution
A pungent spray.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the topical relief of symptoms of musculoskeletal pain such as in lumbago, sciatica, muscle strains.

4.2 Posology and method of administration

Topical

Recommended Dosage Schedules

Adults, the elderly and children 12 years and over

Shake well before use.

Repeat applications at intervals of less than two hours are not recommended.

Hold the container about 6 inches from the skin with the arrow pointing to the site of pain and depress the button to spray in 2-3 short bursts. This may be repeated up to 4 times daily. The spray is rapidly absorbed by the skin and massage is not required.

If, after use, an increased effect is required, cover the sprayed area with a pad of cotton wool held in place by adhesive tape.

Not to be used on children under 12 years of age.

4.3 Contraindications

Salicylate hypersensitivity, or hypersensitivity to any constituents of the spray. Injuries involving broken skin.

4.4 Special warnings and precautions for use

Contact with the eyes and mucous membranes should be avoided.
Hands should be thoroughly washed after contact with product during application.
If you are receiving medication, contact your doctor before using.
If symptoms persist, consult your doctor.
For external use only.
Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

The product is not contraindicated during pregnancy. However, as with all medicines during pregnancy, caution should be exercised.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Skin irritations may occur in certain individuals which may be enhanced after a hot bath or in hot weather.

4.9 Overdose

Over use would probably cause excessive localised redness and burning sensation of the skin owing to the rubefacient action of the product. These would subside on withdrawal of the product. Where treatment is indicated, relief would be obtained from gently swabbing the area with gauze or white lint soaked in vegetable oil. Rarely, the application of a cream or ointment containing corticosteroid may be necessary.

It is most unlikely that even the most excessive use of the product would lead to sufficient percutaneous absorption of active ingredients to cause systemic effects.

Treatment

After withdrawal of the product, the treatment is symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
ATC Code: M02A.

Ethyl salicylate, glycol monosalicylate and methyl salicylate provide topical analgesic and anti-inflammatory effects for the symptomatic relief of muscular aches and pains. Methyl nicotinate is a rubefacient.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Butane 30

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Protect from sunlight and do not expose to temperatures exceeding 50°C.
Do not pierce or burn even after use.
Do not spray on a naked flame or any incandescent material.

6.5 Nature and contents of container

A pressurised aerosol consisting of the following parts:

(a) An internally lacquered tin can containing 125ml or 150ml suspension;
(b) A white actuator with pink insert for manual actuation.

Not all pack sizes may be marketed.

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

Seton Products Ltd
Tubiton House
Oldham
OL1 3HS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0618/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 February 1982

Date of last renewal: 14 May 2007

10 DATE OF REVISION OF THE TEXT

June 2008