

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ralgex Heat Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycol Monosalicylate 6.00 % w/v

Methyl Nicotinate 1.6 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief of muscular pain and stiffness, including backache, sciatica, lumbago, fibrositis and rheumatic pain.

4.2 Posology and method of administration

Method of administration: for external application to the skin:

Adults and children 5 years and over:

Shake well before use.

Hold the container about 6 inches (15cm) from the skin with the arrow pointing to the site of pain and depress the button to spray in 2-3 short bursts. Further applications may be made at intervals of not less than two hours. 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 five years of age.

The Elderly: Normal adult directions for use can be used.

4.3 Contraindications

Hypersensitivity to salicylates (salicylic acid (or other NSAIDs) or any other ingredients. Injuries involving broken or inflamed skin.

4.4 Special warnings and precautions for use

This product contains glycol salicylate and so should be used with caution in patients at increased risk of developing salicylate adverse effects.

Some people experience stronger effects with Ralgex Heat Spray than others; the products should be tried on a small area first.

Avoid inhalation and contact with the eyes, mouth, head, neck or on sensitive body areas or broken skin or on large areas of the body.

Always spray sparingly: over application can cause discomfort.

Day-to-day variation may occur in the sensitivity of the skin, which is more sensitive after a hot bath or in hot weather.

If symptoms persist, consult your doctor

If hands come into contact with the product during application please wash thoroughly. If you are receiving medication, contact your doctor before using.

For external use only. Keep out of the sight and reach of children.

Other precautions are necessary as Ralgex Heat Spray is in a pressurized container.

Caution: Extremely flammable. Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Keep away from sources of ignition - no smoking. Do not spray on a naked flame or any incandescent material. Avoid contact with polished surfaces.

4.5 Interaction with other medicinal products and other forms of interaction

Salicylates in the form of gels, oils, or ointment applied to the skin have been found to increase the effects of warfarin. Bleeding and bruising, and/or raised INRs have been seen with both high and low doses.

4.6 Fertility, pregnancy and lactation

Pregnancy:

No evidence of safety of this product has been determined in pregnancy. It is not necessary to contraindicate this product in pregnancy provided caution is exercised and the directions for use are followed.

However, as with all medicines, the advice of a doctor should be sought before the product is used.

Breast feeding:

Salicylates should be given with caution to breast-feeding mothers because of the possible risk of Reye's syndrome in nursing infants and there is no data on the use of the combination product in breast feeding women.

Fertility:

There is no information on the effects of the product on fertility.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Mild irritation of the skin (reddening, burning sensations and rarely swelling) have been reported, which may be enhanced after a hot bath or in hot weather. Rashes have also been rarely reported.

Although rare, anaphylactic reactions have been reported, symptoms of which may include flushing, shortness of breath and fall in blood pressure.

Glycol Monosalicylate:

Salicylism can also occur following excessive topical application of salicylates. Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, and confusion, and may be controlled by reducing the dosage.

4.9 Overdose

Over use would probably cause excessive localised redness and burning sensation of the skin owing to the counter-irritant effect of the product. Rashes and blisters may also develop.

These should subside on withdrawal of the product, but occasionally may require treatment. Where this 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, although salicylism may occur following excessive topical application. After withdrawal of the product, treatment is symptomatic. In the case of accidental oral ingestion, the advice of a doctor should be sought

Glycol Monosalicylate: Ingestion of salicylates pose the threat of salicylate poisoning. Symptoms are similar to those of salicylate poisoning in general.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain

ATC code: M02A.

Glycol Monosalicylate provides anti-inflammatory and analgesic actions. Methyl Nicotinate has a counter-irritant effect by a rubifacient action. It rapidly penetrates the cutaneous barrier to produce vasodilation and elevation of skin temperature.

Clinical data demonstrate that Ralgex Heat Spray provides an immediate warming effect and rapid warming relief for muscular aches and pains.

5.2 Pharmacokinetic properties

Glycol monosalicylate and methyl nicotinate are readily absorbed percutaneously.

5.3 Preclinical safety data

Preclinical safety data on these active ingredients in the literature has not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol

Butane 30 psig

Goliath Perfume SE 830502

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Protect from sunlight and do not expose to temperatures exceeding 50°C.

Pressurised container - 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

Tin-plate, double lacquered 125 ml or 150 ml aerosol cans fitted with a valve and acutator which are covered with a plastic cap.

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

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8 MARKETING AUTHORISATION NUMBER

PA00257/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 December 1990

Date of last renewal: 11 December 2005

10 DATE OF REVISION OF THE TEXT

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