

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ralgex Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ralgex Cream contains:		
Glycol Monosalicylate	10.0	% w/w
Methyl Nicotinate	1.0	% w/w
Capsicum Oleoresin	0.12	% w/w

Excipients: Contains		
Methylhydroxybenzoate (E218)	0.20	% w/w
Butylhydroxybenzoate (E216)	0.10	% w/w
Emulsifying wax (contains cetostearyl alcohol)	9.0	% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Thick, off-white, homogeneous cream with a characteristic odour.

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 aged 12 years and over:
After trial use, rub into the skin until absorbed.
To be applied as required to the affected area. Repeat as necessary up to four times a day.
Not to be used on children under 12 years except on medical advice.

The elderly:
The normal adult directions for use can be followed.

4.3 Contraindications

Known hypersensitivity to salicylates, salicylic acid (or other NSAIDs) or to any of the ingredients of the cream.
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.

Side effects include local irritation and occasionally allergic reactions.

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

Do not apply near the eyes, mouth or on sensitive body areas. Do not apply to large areas of the body.

If symptoms persist, consult the doctor.

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

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

This cream contains methylhydroxybenzoate (E218) which may cause hypersensitivity (possible delayed) and emulsifying wax of which cetostearyl alcohol may cause local skin reaction (e.g. contact dermatitis).

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 of topical salicylates.

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 and lactation 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 irritations of the skin (reddening, burning sensations and rarely swelling) have been reported, which may become more severe. 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.

Capsicum Oleoresin:

Preparations of capsicum oleoresin can be very irritant to the skin and mucous membranes. Coughing and itching have been reported after use of topical preparations containing capsicum oleoresin.

4.9 Overdose

Overuse would probably cause localised redness, swelling and burning sensations of the skin owing to the counterirritant effect of the product. Rashes 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 this 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: Other topical products for joint and muscular pain, ATC code: M02A.

Methyl nicotinate has a counter-irritant effect by a rubefacient action. It readily penetrates the cutaneous barrier to produce vasodilatation and elevation of skin temperature.

Capsicum oleoresin has a counter-irritant effect by producing irritation and a transient feeling of warmth.

Glycol monosalicylate provides the anti-inflammatory and analgesic action.

Clinical data demonstrate that Ralgex Cream provides 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying Wax (contains cetostearyl alcohol)
Glycerol monostearate with polyoxyethylene stearate
Oleyl Alcohol
Dimeticone
Methylhydroxybenzoate (E218)
Butylhydroxybenzoate (E216)
Goliath perfume SE 83.0502
Neutrolaire D7
Deionised water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Flexible aluminium tubes (containing 5 g, 15g, 40g, 44g, 80g, 88g, 100g or 110g of product), internally lacquered and having a white polypropylene screw cap. The tubes may be contained in a boxboard carton.

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

GR Lane Health Products Ltd
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8 MARKETING AUTHORISATION NUMBER

PA0257/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 June 1992

Date of last renewal: 16 June 2007

10 DATE OF REVISION OF THE TEXT

February 2015