

1 NAME OF THE MEDICINAL PRODUCT

Radian B Muscle Rub

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Menthol	2.54% w/w
Camphor	1.41% w/w
Methyl Salicylate	0.42% w/w
Camphor Oil, White	0.32% w/w
Oleoresin Capsicum	0.005% w/w
Camphor and Camphor Oil, White are collectively declared as: Camphor	1.43% w/w
<u>Excipient(s) with known effect</u>	
Emulsifying Wax (containing Sodium laurilsulfate and Cetostearyl alcohol)	9.70%
For the full list of excipients, see section 6.1.	

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of rheumatic pains and mild muscle pains.

4.2 Posology and method of administration

For external use application

Adults and children over 6

Apply to the affected parts and slowly massage well into the skin. For muscular strains and stiffness it is best used after a hot bath. Repeat application up to three times daily, reducing to morning and evening when acute symptoms subside.

Elderly

The adult dose is appropriate.

Children

Do not use on children under 6 years old.

4.3 Contraindications

Hypersensitivity to salicylates, to other active substances or to any of the excipients listed in section 6.1. If irritation develops, use of the product should be discontinued.

Not to be used on children under 6 years old.

Do not apply to skin abrasions.

Do not apply to irritated skin.

4.4 Special warnings and precautions for use

Keep away from eyes and sensitive areas. If symptoms persist consult a doctor.

Wash hands thoroughly after use.

The excipients cetostearyl alcohol, lanolin and 0.91% w/w sodium laurilsulfate may cause local skin reactions (e.g. contact dermatitis, stinging or burning sensations) or increased skin reactions caused by other products when applied to the same area.

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. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

4.6 Fertility, Pregnancy and lactation

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Radian B Muscle Rub should only be used during pregnancy or lactation when there is no safer alternative.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Use sparingly on tender skin and do not cover immediately after application. If an adverse reaction occurs discontinue use immediately. Known side effects of menthol – contact dermatitis or eczema, hypersensitivity reactions characterised by urticaria, flushing and headache. Irritation of the skin may also be caused by the capsicum oleoresin in this product.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il>

4.9 Overdose

When used externally as directed, overdose is unlikely. However, symptoms of systemic salicylate poisoning have been reported after the application of salicylates to large areas of skin or for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested.

Salicylate poisoning

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management

Activated charcoal may be administered if significant quantities have been ingested within an hour of presentation. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

Camphor and Menthol

Ingestion of the product or excessive use may also lead to camphor poisoning, the symptoms of which include nausea, vomiting, epigastric pain, headache, dizziness, oropharyngeal burning, delirium, muscle twitching, epileptiform convulsions, CNS depression and coma. Breathing is difficult and the breath has a characteristic odour; anuria may occur. Death from respiratory failure or status epilepticus may occur; fatalities in children have been recorded from 1g. Supportive care, including anticonvulsant therapy, is the mainstay of treatment of camphor intoxication. Gastric lavage may be considered if the patient presents within 1 hour of ingestion; any convulsions must be controlled first. Activated charcoal may be given orally.

Ingestion of significant quantities of menthol is reported to cause symptoms similar to those seen after ingestion of camphor, including severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma; they may be managed similarly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Radian B Muscle Rub is a smooth, off-white cream which incorporates menthol, camphor, methyl salicylate, Oleoresin Capsicum and white camphor oil as active ingredients.

Menthol relieves itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect. Camphor acts as a rubefacient and mild analgesic and is employed as a counter-irritant. Methyl salicylate has the actions of the salicylates. It is readily absorbed through the skin and has counter-irritant properties. Oleoresin Capsicum has counter-irritant properties and white camphor oil is a rubefacient and mild counter-irritant.

5.2 Pharmacokinetic properties

None available

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Argobase S.1

(Contains: lanolin
lanolin alcohol
cetostearyl alcohol
liquid paraffin)

Emulsifying wax

(Contains: cetostearyl alcohol
sodium lauril sulfate)

White petroleum jelly

Industrial methylated spirit

Imidurea

2,4-dichlorobenzyl alcohol

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 56 days.

6.4 Special precautions for storage

Store below 25°C

Inflammable, Keep away from heat and fire.

6.5 Nature and contents of container

Lacquered aluminium tube and plastic cap. White plastic screw-cap jar.

Pack sizes: 40, 100 grams.

Not all package size may be marketed.

6.6 Special precautions for disposal

No special precautions necessary

7 MANUFACTURER

Thornton & Ross Limited

Huddersfield

West Yorkshire

HD7 5QH

United Kingdom

8 REGISTRATION HOLDER

Devries & CO. LTD

32 HaBarzel ST., Tel Aviv

9 REGISTRATION NUMBER

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