1 NAME OF THE MEDICINAL PRODUCT

Radian B Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Menthol	1.4	%w/v	
Acetylsalicylic Acid	1.2	%w/v	
Camphor		0.6	%w/v
Methyl Salicylate	0.6	%w/v	

Excipients with known effect:

Citronella oil (contains geraniol, citronellol, Eugenol, benzyl benzoate, citral)	1.00	%w/v
Industrial methylated spirit	80.0%	%w/v

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Spray for topical application to human beings.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of light muscular and rheumatic pains.

4.2 Posology and method of administration

For external application

For Adults and Children over 12 years:

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

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.

Elderly:

The adult dose is appropriate.

Children Under 12:

Do not use on children under 12 years of age.

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.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Contraindicated where there is known hypersensitivity to aspirin, other salicylates, or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.

If irritation develops, use of the product should be discontinued.

Pregnancy and lactation.

4.4 Special warnings and precautions for use

Do not use near the face, eyes and other sensitive areas. If symptoms persist, consult a doctor.

Wash hands thoroughly after use.

Flammable: Do not spray near naked flame or hot surface. Should not be placed on or used near polished or painted surfaces. Do not use in confined spaces and avoid inhaling the spray.

Instruct patients not to smoke or go near naked flames- risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipient warnings:

This medicine contains fragrance with Geraniol, Citronellol, Benzyl Benzoate, Eugenol and Citral which may cause allergic reactions.

This medicine contains 76% v/v ethanol per application. This may cause burning sensation on damaged skin.

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 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

If used on tender skin 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.

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. limination 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 1 g. 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 spray is manufactured using the following active ingredients; menthol, camphor, aspirin and methyl salicylate. The finished product contains menthol, camphor, ammonium salicylate and a mixture of methyl and ethyl esters of salicylic acid. The product provides salicylate ions which have analgesic properties. Methyl and ethyl salicylate are readily absorbed through the skin and have counter-irritant properties. 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.

5.2 Pharmacokinetic properties

The active ingredients are well-documented pharmacopoeial ingredients. The extent of percutaneous absorption in human volunteers of (14C) acetyl salicylic acid from Radian B spray was studied and estimated by measurement of blood and urinary concentrations of radioactivity. Significant absorption through the skin was indicated by the excretion of almost 10% of the applied radioactivity in the urine within 5 days with approximately 5.5% in the first 24 hours.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial methyated spirit

Glycerol

Citronella oil

Ammonia solution 33%

Water (purified)

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

Store below 25°C.

Inflammable, Keep away from heat and fire.

6.5 Nature and contents of container

100ml: HDPE bottle pump action spray unit with a polypropylene cap.

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., 69710 Tel Aviv

9 REGISTRATION NUMBER

137-63-24791

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