SUMMARY OF PRODUCT CHARACTERISTICS

RUBEM CREAM

Table of Contents

1. Name of the medicinal product
a) Proprietary name of a medicine
Rubem Cream
b) Approved generic name(s)
Methyl Nicotinate 1%, Capsicum oleoresin 0.1%, Methyl Salicylate 5%
2 Qualitative and quantitative composition
Each gm. Contains, Methyl Nicotinate 1%, Capsicum oleoresin 0.1%, Methyl Salicylate 5% For Excipients 6.1
3 Pharmaceutical form Dosage form
Cream
4 Clinical particulars

4.1 Therapeutic indication(s)

For the relief of muscular aches and pains and stiffness including Rheumatic pain, Sciatica, Lumbago, Backache, Cramps and sprains.

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.

Elderly

The adult dose is appropriate.

Children

Do not use on children under 6 years old.

4.3 Contra-indications

Not to be used on children under 6 years old.

Do not apply to skin abrasions.

Do not apply to irritated skin.

Contraindicated in patients who are hypersensitive to salicylates or to any other ingredient in the preparation. If irritation develops, use of the product should be discontinued.

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.

Labels state:

Keep out of the reach and sight of children.

For external use only.

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4.5 Interactions

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin.

4.6 Pregnancy and lactation

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

Effects on the ability to drive and operate machinery

Not applicable

4.6 Undesirable effects:

Use sparingly on tender skin and do not cover immediately after application. If an adverse reaction occurs discontinue use immediately.

4.7 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.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Methyl salicylate has the actions of the salicylates. It is readily absorbed through the skin and has counter-irritant properties. Capsaicin has counter-irritant properties and white camphor oil is a rubefacient and mild counter-irritant.

5.2 Pharmacokinetic properties

None available

5.4 Preclinical safety data

None available

6 Pharmaceutical particulars

6.1 List of excipients

Glycerine
Triethanolamine
Chlorocresol
White Soft Paraffin
Liquid Paraffin
Emulsifying wax
Stearic Acid

6.2 Incompatibilities - None known.

6.3Shelf-life -

- In the original unopened container; 36 months
- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

Special precautions for storage:

Rubem should be stored below 25°C, in a dry and dark place.

Keep out of the reach of children

6.4 **Nature and composition of containers**

Pack Size: 25g. Rubem Cream aluminum Tubes, Rubem Cream Leaflets, Rubem Cream unit cartons,

Instruction for use/handling

For external use only

Wash hands before and after use.

Restriction on sale / distribution:

Prescription only medicine (POM)

7 Administrative data

i. **Name and address of holder of a registration.**

Regal Pharmaceuticals Limited

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8.i Registration number. - 4460

ii. Date of first registration- 13/02/2008