

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Menthol and Wintergreen Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Eucalyptus Oil	1.30% w/w
Menthol	0.23% w/w
Methyl Salicylate	11.22% w/w
Thymol	0.75% w/w
Camphor	0.38% w/w
Volatile Mustard Oil	0.07% w/w

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cream for Topical Application

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is recommended for the symptomatic relief of rheumatic pains, stiff neck, chilblains and sprains

4.2 Posology and method of administration

For topical administration.

Apply to the affected parts two to three times daily. If symptoms persist consult your doctor.

4.3 Contraindications

Hypersensitivity to:

1. Eucalyptus Oil
2. Menthol
3. Thymol
4. Camphor
5. Volatile Oil of Mustard

4.4 Special warnings and precautions for use

For external use only.

Not to be applied to sensitive or broken skin.

If symptoms persist consult your doctor.

Keep out of the sight and reach of children

Menthol and Wintergreen contains arachis oil (Peanut oil) and should not be taken/applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Menthol and Wintergreen.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

There are no limitations on the use of this product during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Very rarely menthol present in the formulation may cause contact dermatitis.

4.9 Overdose

In the case of accidents oral ingestion:

- D) Mild intoxication - patient should be encouraged to drink plenty of fluids.

II) Severe intoxication - forced alkaline diuresis may be required. Plasma electrolytes, especially potassium and acid-base balance should be monitored. Repeated doses of oral suspensions of activated charcoal may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Eucalyptus oil is a rubefacient causing an initial sensation of warmth and smarting followed by mild local anaesthesia. Menthol produces dilatation of skin blood vessels, with an initial sensation of coldness followed by an analgesic effect. Methyl salicylate is employed topically for cutaneous counter-irritation property, its analgesic and anti-inflammatory action is due to inhibition of biosynthesis of prostaglandins. Thymol has disinfectant and fungicidal properties. It is employed in the cream for its analgesic effect. Camphor is a mild analgesic, rubefacient and counter irritant. It is rubefacient when rubbed onto the skin. When not vigorously applied, it may produce a feeling of coolness together with a mild local anaesthetic action; its application to the skin may be followed by numbness. Volatile mustard oil is an irritant to the skin and acts as a counter irritant and rubefacient.

5.2 Pharmacokinetic properties

Eucalyptus oil, menthol, thymol, volatile mustard oil, camphor and methyl salicylate act locally on the surface of the skin. Methyl salicylate and camphor can be absorbed through the skin. When absorbed through the skin, methyl salicylate has an analgesic and anti-inflammatory action due to inhibition of biosynthesis of prostaglandins. Camphor is employed for its local action. When absorbed through the skin it is hydroxylated in the liver to yield hydroxycamphor metabolites which are then conjugated with glucuronic acid and excreted in the urine.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Irish Moss Extract

Arachis Oil

Oleic Acid

Wool Fat

Citric Acid Monohydrate
Potable Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months unopened.

6.4 Special precautions for storage

Store in a cool place, below 25°C.

6.5 Nature and contents of container

Amber glass jar with plastic wadded screw cap, size: 100g or
Aluminium tubes, size: 100g

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

STERLING PHARMACEUTICALS LIMITED

288 UPPER BALSALL HEATH ROAD

BIRMINGHAM

B12 9DR

UNITED KINGDOM

8 MARKETING AUTHORISATION NUMBER(S)

PL 32515/0003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

Date of grant 15th January 2001

10 DATE OF REVISION OF THE TEXT

07/04/2008