

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Methyl Salicylate Liniment B.P.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl Salicylate 25.0% v/v

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Liniment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of muscular and rheumatic pains, sciatica, lumbago, fibrositis, sprains and strains of ligaments and tendons, bruises and muscle stiffness.

4.2 Posology and method of administration

Adults, children and the elderly

Rub in gently as required.

4.3 Contraindications

Hypersensitivity to arachis oil and sensitivity to salicylates.

4.4 Special warnings and precautions for use

Methyl Salicylate Liniment B.P. contains arachis oil (peanut oil) and should not be 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 Methyl Salicylate Liniment B.P.

The product is for external use only and should not be taken by mouth. Contact with eyes, mucous membrane, inflamed or broken skin should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

Potential of warfarin anticoagulation has been reported following topical application of methyl salicylate.

4.6 Pregnancy and lactation

No significant problems have been reported thought, as with all medicines, it should be used under medical supervision in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Urticaria and angioedema have been reported in aspirin-sensitive patients.

4.9 Overdose

As the product is for topical use the likelihood of overdose due to ingestion is small. Should it occur then treatment includes induction of emesis followed by supportive therapy accompanied by gastric lavage. Charcoal haemoperfusion has been used in the treatment of poisoning with methyl salicylate. As little as 4 ml has caused death in infants.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Methyl salicylate is absorbed through the skin and relieves pain in rheumatic and other conditions of sprains and muscle stiffness etc.

5.2 Pharmacokinetic properties

Methyl salicylate is absorbed through the skin.

It is rapidly hydrolysed to salicylic acid, mainly in the liver and excreted, mainly by the kidney, as salicylic acid, as salicyluric acid, as salicylic phenolic and acyl glucuronide, and as gentisic acid. The excretion is pH dependent with up to 30% being excreted as salicylic acid under alkaline conditions and as low as 2% under acid conditions.

The plasma half- life of salicylates is 2-3 hours.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis Oil

6.2 Incompatibilities

No significant incompatibilities have been reported though it is a “phenol” and as such will react with certain metal salts e.g. iron.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25⁰C.

6.5 Nature and contents of container

500 ml and 2000 ml dispensing packs:

Amber glass bottle with a white plastic screw cap with an aluminium foil lined EPE liner.

Patient packs or OTC packs as appropriate:

100 ml and 200 ml amber glass bottles with plastic Jay cap closures.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 18374/0030

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

14th April 2005

10 DATE OF REVISION OF THE TEXT

14/04/2005