SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mentholatum Balm or
Mentholatum Vapour Rub
Lloydspharmacy Vapour Rub

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl salicylate	0.33% w/w
Menthol	1.35% w/w
Camphor	9.00% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical application to the skin or inhalation.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of:

i) colds, catarrh and hay fever

ii) muscular pain and stiffness, including backache, sciatica, lumbago, fibrositis, rheumatic pain, bruises and chilblains.

iii) minor skin conditions (including dry and chapped skin, nettle rash, insect bites and stings, itching).

4.2 Posology and method of administration

<u>For adults and children over 3 years</u>

To be applied 2-3 times daily

Directions for use: -

i) Allow inhalation of the vapour following either (a) rubbing onto the chest, neck and back, or (b) melting one teaspoonful in hot water.

ii) Rub onto the affected area

iii) Dab a small amount lightly onto the affected skin.

Do not apply under the nostrils in children.

4.3. Contraindications

Hypersensitivity to any of the components of the formulation. Hypersensitivity to aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (including when taken by mouth), especially where associated with a history of asthma.

4.4 Special warnings and precautions for use

For external use and only on unbroken skin. The product should not be applied to delicate skin.
Asthma – caution is required as salicylates may provoke bronchospasm in patients with asthma (see section 4.3).
Pregnancy and breast feeding – avoid use unless necessary (see section 4.6)
Interactions – salicylates can increase the effect of anticoagulants and antiplatelet medications (see section 4.5).
Avoid contact with the eyes and sensitive areas of skin. Always try on a small area first. Wash hands immediately after use. Discontinue use if excessive irritation or other unwanted effects occur. If symptoms persist consult your doctor. Not for use with occlusive dressings. Keep site of application to the body uncovered or loosely covered. Do not use on children under 3 years old. Ingestion of even small amounts in young children is harmful. Keep all medicines out of the sight and reach of children.

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."

4.5 Interaction with other medicinal products and other forms of interaction

Although no adequately controlled interaction studies have been undertaken, it is possible that excessive use of topical salicylates may increase the effect of coumarin anticoagulants and antiplatelet medications. Patients who are taking coumarin anticoagulants or antiplatelet medications, including aspirin, should therefore exercise caution.

4.6. Pregnancy and lactation

There are no adequate data from the use of this product during pregnancy or breast-feeding upon which to base specific advice. Salicylates are aspirin-like substances; therefore similar cautions as appropriate for aspirin are advised. As with all medicinal products, use during pregnancy or breast-feeding should be avoided unless considered necessary.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Temporary skin reactions such as redness, burning sensation, rashes may occur. Application site burns have been reported. Frequency unknown.

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. Healthcare professionals are asked to report any suspected adverse reactions via:

Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Over dosage may result in skin irritation.

Misuse:

Swallowing of the ointment might cause gastrointestinal symptoms like vomiting and diarrhoea. Treatment is symptomatic.

Acute poisoning was observed after significant accidental consumption, with nausea, vomiting, abdominal pain, and headache, vertigo, feeling hot / flushing, convulsions, respiratory depression and coma.

Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Inhalation of the vapour has a decongestant action.
Methyl salicylate is an aspirin-like drug used for pain relief.
Menthol when applied topically provides analgesia.
Camphor when applied topically acts as a rubefacient and mild analgesic.

5.2. Pharmacokinetic properties

The product is for topical administration. No absorption studies have been carried out with this product. Data from the published literature on the active ingredients can be summarised as follows:

Methyl salicylate is readily absorbed from topical preparations and this absorption is enhanced by heat, exercise, occlusion and disruption to the skin surface. Rapid local hydrolysis to salicylic acid in tissues results in low systemic plasma concentrations of methyl salicylate after topical application. Topical application of methyl salicylate is therefore likely to exert local effects only. Systemic salicylic acid becomes extensively protein bound in an inactive form and the free active form is metabolised or excreted unchanged in the urine.

Pharmacokinetic information following topical application of menthol is limited. Menthol is absorbed across the skin with relatively low systemic plasma concentrations indicating that the effects of topical menthol are likely to be predominantly local in nature. There is thought to be some metabolism of topical menthol in the skin, but the majority is metabolised by the liver, which converts the lipid soluble menthol into four water-soluble metabolites that are excreted in the urine.

Very little is known about pharmacokinetic properties of camphor following topical application.

5.3. Preclinical safety data

No toxicology testing of the product has been undertaken. However all the active ingredients are subject to monographs in the British and European Pharmacopoeias and are documented in Martindale, The Complete Drug Reference.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eucalyptus Oil
Pumilio Pine Oil
Titanium Dioxide
Yellow Soft Paraffin

6.2. Incompatibilities

None known

6.3. Shelf Life

3 years.

6.4. Special Precautions for Storage

No special precautions.

6.5. Nature and contents of container

Printed, collapsible aluminium tube filled to an average weight of 25g with screw cap.

Polystyrene plastic jar filled to an average weight of 30g, with a printed label and a polysan lined polypropylene screw cap enclosed in a cardboard carton.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

Any unused product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited
1 Redwood Avenue
Peel Park Campus
East Kilbride
G74 5PE
Scotland
UK

8. MARKETING AUTHORISATION NUMBERS

PL 00189/5001R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 March 1985 / 25 July 1996

10. DATE OF REVISION OF THE TEXT

November 2004

10 DATE OF REVISION OF THE TEXT

08/11/2019