SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Menthol and Wintergreen Vapour Rub

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Actives	Quantity	Unit	Ref
Cajuput Oil	2.5	% V/W	BPC
Camphor	2.5	% W/W	BP
Cineole	2.5	% V/W	BPC
Menthol	5.0	% W/W	BP
Methyl Salicylate	15.0	% V/W	BP

3 PHARMACEUTICAL FORM

Ointment.
A smooth homogenous off-white ointment, similar to white petroleum jelly.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of muscular pain, rheumatic pain, fibrositis, sciatica, strains, lumbago, colds.

4.2 Posology and method of administration

Adults, elderly and children over 3 months, use as directed, two to three times daily.

Do not give to children under 3 months old.

4.3 Contraindications

Menthol and Wintergreen Vapour Rub is contraindicated in patients with known hypersensitivity to any of the listed actives or the excipients (see section 6.1).
Hypersensitivity to aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.
Children under 3 months

4.4 Special warnings and precautions for use

For external use only.
Keep out of the sight and reach of children.

For use as an inhalant
Use with caution in patients with asthma (see section 4.8).

Cutaneous use
Do not use if the patient is taking warfarin unless clinically necessary (see section 4.5).

Do not use if you are allergic to any of the ingredients or painkillers such as aspirin, ibuprofen and other NSAIDs. Consult your doctor before use if you are pregnant, breast-feeding, asthmatic or on any prescribed medicines. For external use and only on unbroken skin. Avoid contact with the eyes and sensitive areas of skin.

If symptoms persist or worsen after 2 weeks, a physician should be consulted.
Eye contact with unwashed hands after application may potentially cause irritation.
Do not apply to broken skin or mucous membranes.
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Pregnancy and breast-feeding – avoid use unless necessary (see section 4.6).

Asthma – caution is required as salicylates may provoke bronchospasm in patients with asthma (see section 4.3).

Interactions – salicylates can increase the effect of anticoagulants and antiplatelet medications (see section 4.5).

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."

Always try on a small area first. Some people may experience discomfort particularly those with sensitive skin or if used in hot weather or after a bath. Not for use with occlusive dressings. Wash hands immediately after use.

Discontinue use if excessive irritation or other unwanted effects occur.

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 Fertility, pregnancy and lactation

There are no adequate data from the use of this product during pregnancy or breastfeeding 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

The following undesirable effects have been reported in post-marketing experience for the active substances in this product. The frequency of undesirable effects considered at least possibly related to treatment is unknown (cannot be estimated from available data).

Immune system disorders
Hypersensitivity reactions including: asthma, rhinitis and contact dermatitis. It is possible that skin burns, blisters and temporary skin reactions such as redness, burning sensation and rashes may occur.

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

4.9 Overdose

Overdose is unlikely when used as recommended.

If applied to a large area of skin, or in the unlikely event of oral ingestion, the product may cause systemic adverse effects depending on the amount absorbed.
In the event of overdose treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code:
Cajuput Oil: No code found
Camphor: C01EB03
Cineole: No code found
Menthol: M02AC87 (in combination with methyl salicylate)
Methyl Salicylate: M02AC87 (in combination with menthol)

The properties of the five active constituents when applied topically are as follows:
Menthol dilates the blood vessels, causing a sensation of coldness followed by an analgesic effect. Menthol when applied topically provides analgesia.
Camphor acts as a rubefacient and mild analgesic.
Cineole is a rubefacient.
Cajuput oil is a stimulant and mild rubefacient.
Wintergreen/ Methyl Salicylate relieves pain.
Methyl salicylate is an aspirin like drug used for pain relief.

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 metabolized 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.

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

White Soft Paraffin BP 70.1% W/W

6.2 Incompatibilities

None stated

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a cool place

6.5 Nature and contents of container

White polypropylene jar with white R3/48mm polypropylene screw cap (enclosed in a cardboard carton)

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

Bell Sons and Company (Druggists) Limited,
Gifford House,
Slaidburn Crescent,
Southport,
PR9 9AL,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 03105/0110

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/01/2012

10 DATE OF REVISION OF THE TEXT

17/04/2024