

1. NAME OF THE MEDICINAL PRODUCT

Bell's Muscle Rub
Wilko Muscle Rub
Numark Muscle Rub
Superdrug Muscle Rub
Sainsbury's Muscle Rub Ointment
Asda Muscle Rub Ointment
Well Pharmaceuticals Muscle Rub Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of ointment contains:

Cajuput Oil	0.12 % v/w
Eucalyptus Oil	1.00 % v/w
Levomenthol	0.5 % w/w
Methyl Salicylate	9.12 % v/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment

Off white / pale yellow semi translucent ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of pain in arthritis, rheumatism, lumbago, sciatica and other muscular and rheumatic conditions by application to the skin.

4.2 Posology and method of administration

For cutaneous use only.

Always try on a small area first

Wash hands before and after use.

Adults, elderly and children over 5 years of age.

Massage gently into the affected area two or three times daily.

Not recommended for use in children under 5 years of age.
(See Section 4.4 'Special warnings and precautions for use.')

If symptoms worsen, or persist after 2 weeks, a doctor should be consulted.

4.3 *Contraindications*

Hypersensitivity to any of the active ingredients, 1,8-cineol or any of the other ingredients.

Children with history of seizures (febrile or not).

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

4.4 *Special warnings and precautions for use*

Do not exceed the stated dose.

For cutaneous use only.

Avoid contact with eyes and mucous membranes.

Eye contact with unwashed hands may potentially cause irritation.

Do not apply to broken or irritated skin.

Discontinue use if redness or irritation occurs.

If symptoms worsen, or persist after 2 weeks, a doctor should be consulted.

If articular pain accompanied by swelling of the joints, redness or fever occurs, a doctor should be consulted.

The use in children under 5 years of age is not recommended because data are not sufficient and medical advice should be sought.

Oral alicylates (aspirin) can sometimes be associated with aggravation of active peptic ulcers, and can induce allergic bronchial reactions in susceptible asthmatic patients. Although the systemic absorption of topically applied methyl salicylate is less than for oral dosage forms, these complications can occur in rare cases. For these reasons, patients with an active peptic ulcer or asthma should seek medical advice before using this product as should patients already taking other painkillers.

Oral salicylates taken during or immediately after a viral illness have been associated with Reye's syndrome and hence there is a theoretical risk with topical salicylates. Therefore, use is not advised in children or teenagers during or immediately after chickenpox, influenza, or other viral infections.

Do 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

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

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Skin irritation may rarely occur.

If other adverse reactions not mentioned above occur, a doctor should be consulted.

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. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 *Pharmacodynamic properties*

Methyl Salicylate has the action of salicylates, i.e. analgesic and anti-inflammatory.

Levomenthol provides an analgesic effect.

Eucalyptus oil is used for its rubifacient action, providing a warming of the skin and a counter irritant for the relief of muscular pain.

Cajuput oil contains cineol (eucalyptol) and has the actions of eucalyptus oil.

5.2 Pharmacokinetic properties

Methyl salicylate is readily absorbed through the skin.

Levomenthol when applied to the skin, dilates the vessels causing a sensation of coldness followed by an analgesic effect.

Eucalyptus oil causes a reddening of skin.

5.3 Preclinical safety data

None available

6 PHARMACEUTICAL PARTICULARS

6.1 *List of excipients*

Paraffin Wax

White Soft Paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

36 months in unopened container.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Amber glass jar with screw cap lid.
25 gm, 30 gm, 85 gm.
Aluminium tubes with polypropylene caps.
25 gm, 30 gm, 40 gm.

6.6 Instructions for use/handling

No special instructions

7 MARKETING AUTHORISATION HOLDER

Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8 MARKETING AUTHORISATION NUMBER(S)

PL 03105/0022

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

Date of grant 26 March 1984
Date of renewal 23 August 1999

10 DATE OF REVISION OF THE TEXT

19/02/2020