

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Seven in One Rubbing Oils.

Bell's Seven in One Rubbing Oil.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl Salicylate BP 7% w/w

3. PHARMACEUTICAL FORM

Topical solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of muscular pain and stiffness including backache, sciatica, lumbago, fibrositis and rheumatic pain.

4.2. Posology and Method of Administration

Topical

Adults, including the elderly and children over 12 years.

Apply to the affected area and rub in gently whenever required up to 3 times a day.

Not recommended for children under 12.

4.3. Contra-indications

Hypersensitivity to salicylates or other ingredients.

4.4. Special Warnings and Precautions for Use

Do not use on broken skin.

For external use only.

Keep out of reach of children.

4.5. Interaction with other Medicaments and other forms of Interaction

None known

4.6. Pregnancy and Lactation

Avoid use during pregnancy and breast-feeding.

4.7. Effects on Ability to Drive and Use Machines

None

4.8. Undesirable Effects

Sensitivity to the product may cause a pain or itching.

Turpentine oil may cause vesicular eruption, urticaria and vomiting in susceptible persons.

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.

4.9. Overdose

If accidentally ingested seek medical advice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Methyl salicylate is readily absorbed through the skin and is used for pain relief. The essential oils when applied to the skin have an irritant and rubefacient action causing first a sensation of warmth and smarting which is followed by a mild local anaesthesia. They are therefore used as counterirritants and cutaneous stimulants in the treatment of chronic inflammatory conditions and to relieve neuralgia and rheumatic pains.

5.2. Pharmacokinetic Properties

Methyl salicylate is readily absorbed into the body and hydrolysis to salicylic acid occurs rapidly which is excreted in the urine. Data on turpentine oil is not readily available.

5.3. Preclinical Safety Data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Nutmeg Oil BP
Thyme Oil BPC 1949
Eucalyptus Oil BP
Turpentine Oil BP
Synthetic Camphor Oil
Pumilio Pine Oil BP 1980
Technical White Oil

6.2. Incompatibilities

None known.

6.3. Shelf Life

60 months in unopened bottle

6.4. Special Precautions for Storage

Do not store above 25°C. Store in the original container.

6.5. Nature and Contents of Container

Amber glass bottles with wadless plastic caps.
Sizes: 15ml, 25ml, 28 ml, 50 ml, 60ml, 75ml, and 100ml

6.6. Instruction for Use/Handling

None

7. MARKETING AUTHORISATION HOLDER

Name or style and permanent address or registered place of business of the holder of the marketing authorisation.

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

8. MARKETING AUTHORISATION NUMBER

PL 03105/0053

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of grant 18 August 1997
Date of renewal 17 July 2000

10. DATE OF REVISION OF THE TEXT

1st April 2016.