

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PAHRMASAL (Methyl Salicylate, Methyl Nicotinate, and Capsicum Oleoresin Ointment)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Quantity per dosage unit in % w/w
Methyl Nicotinate BP	1.0
Methyl Salicylate BP	5.0
Capsicum Oleoresin USP	0.1
Liquid Paraffin Heavy BP	10.0
Petroleum Jelly White BP	83.90

Defination:

BP: British Pharmacopoeia

USP : United states Pharmacopoeia

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Ointment (Topical)

A light brown to dark brownish, smooth homogenous, semisolid, non-gritty ointment free from any visible particle.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatism, muscular pains, fibrositis, stiffness of hounts & pains associated with lumbago and spondylosis. Also for relieving distress of cold.

4.2 Posology and method of administration

Rub the ointment gently on the affected areas until the Ointment is absorbed. Use as and when required.

Please do not apply on broken skin. Contact with eyes or mucous membrane should be avoided.

4.3 Contraindications

Patients manifesting idiosyncrasy to salicylate.

4.4 Special warnings and precautions for use

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Pharmasal Ointment should only be used during pregnancy or lactation when there is no safer alternative i) In case of unbearable burning sensation or any other side effects, please see a medical practitioner. ii) If you are not sure how to use, contact your doctor or pharmacist for advice. iii) Do not use on sensitive skin.

4.5 Interaction with other medicinal products and other forms of interaction

Please tell your health care provider if you are taking or have recently taken following medicines:

Aspirin and anti-coagulant (medicines that help to prevent blood clots).

4.6 Pregnancy and lactation

Pregnancy and breast-feeding: There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Pharmasal Ointment should only be used during pregnancy or lactation when there is no safer alternative.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Use sparingly on tender skin and do not cover immediately after application. If an adverse reaction occurs discontinue use immediately.

4.9 Overdose

When used externally as directed, overdose is unlikely.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Topical preparation product analgesic anti-inflammatory for joint and muscular pain, Non-steroids for topical use

ATC code: M02A

5.1 Pharmacodynamic properties

Methyl Salicylate is novel analgesic anti-inflammatory salicylate acting via the transdermal route. It inhibits the synthesis of lipid peroxides and prostaglandins responsible for stimulating pain receptors.

Capsicum oleoresin is specifically used as counter-irritant in lumbago and rheumatism. The essential oils use constitute a suitable rubefacient base, with their analgesic antiseptic properties and stimulating fragrance.

Hence Pharmasal derives its efficacy from this special formulation to provide an instant relief in painful muscular skeletal conditions..

5.2 Pharmacokinetic properties

Methyl salicylate and methyl nicotinate are readily absorbed percutaneously.

5.3 Preclinical safety data

No additional data of relevance.

6. PHARMACEUTICAL PARTICULARS

Go to top of the page **6.1 List of excipients**

Liquid Paraffin Heavy BP, Petroleum Jelly White BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

25 gm aluminium collapsible tube packed in inner carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None.

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SHALINA HEALTHCARE KENYA LIMITED

ADDRESS: Shalina House, Baba Dogo Road
P.O.Box 39597 - 00623, Nairobi, Kenya

Manufactured by :

8. MANUFACTURER

SHALINA LABORATORIES PVT. LTD.

96, Maker Chambers VI, Nariman Point,
Mumbai-India. www.shalina.com

Manufactured at :

Gopaldas Visram & Company Limited

A 590/591. T.T.C. Industrial Area, Mahape, Navi Mumbai - 400710. India.

8. MARKETING AUTHORISATION NUMBER(S)

H2006/17609/546

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

09/07/2006

10. DATE OF REVISION OF THE TEXT

16-06-2026