SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Salimia Liniment

Strength

Each 100ml contains: Turpentine Oil 25.0ml, Methyl Salicylate 5.0ml, Capsicum Oleoresin 0.22g, Camphor Synthetic 2g and Ammonia Solution Forte 0.12ml.

Pharmaceutical Form

Liniment for topical application

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Qualitative Declaration

Turpentine Oil, Methyl Salicylate, Camphor Synthetic, Capsicum Oleoresin & Ammonium Solution Forte Liniment

Quantitative Declaration

Each 100ml contains: Turpentine Oil 25.0ml
Methyl Salicylate 5.0ml
Capsicum Oleoresin 0.22g
Camphor Synthetic 2g
Ammonia Solution Forte 0.12ml

For the full list of excipients, see section 6.1

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Active Substances

- Turpentine Oil
- Methyl Salicylate
- Camphor Synthetic
- Capsicum Oleoresin
- Ammonium Solution Forte Liniment

3. PHARMACEUTICAL FORM

Liniment for topical application

A clear red liquid with a strong characteristic ammoniacal odor.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is indicated for relief of pain associated with musculoskeletal soreness and discomfort as in arthritis, rheumatism and bursitis.

4.2 Posology and Method of Administration

Posology

- Adults and children over 5 years of age- Apply Salimia Liniment using cotton wool or a clean cloth to the affected area 3 to 4 times daily.

Method of Administration

Topical administration

4.3 Contraindications

In patients with aspirin or salicylate idiosyncrasy

4.4 Special Warnings and Precautions for Use

Special Warnings

FOR EXTERNAL USE ONLY

Contact with eyes, irritation or broken skin should be avoided. Area should not be bandaged tightly. Hands must be washed after the application.

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

No clinical data on the effect of use during pregnancy and lactation. Salimia Liniment should be used with caution in pregnancy and lactation.

4.7 Effects on Ability to Drive and use Machines

Has exhibited no known adverse systemic effects

4.8 Adverse Effects

Patients may feel warm stinging or burning sensation at the site of application, especially during initial few days of use

4.9 Overdose

None known

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group*:* Topical products for joint and muscular pain

ATC Code*:* M02AX

Mechanism of Action

Salimia Liniment is manufactured using the following active ingredients, Turpentine Oil, Methyl Salicylate, Camphor Synthetic, Capsicum Oleoresin & Ammonium Solution Forte Liniment. The product provides salicylate ions which have analgesic properties.

Methyl salicylate is readily absorbed through the skin and has counter-irritant properties. Methyl salicylate itching dilates the vessels causing a sensation of coldness followed by an analgesic effect. Camphor acts as a rubefacient and mild analgesic and is employed as a counter-irritant.

5.2 Pharmacokinetic Properties

The active ingredients are well-documented pharmacopoeial ingredients. The extent of percutaneous absorption in human volunteers of Methyl salicylate from Salimia Liniment was studied and estimated by measurement of blood and urinary concentrations of radioactivity. Significant absorption through the skin was indicated by the excretion of almost 10% of the applied radioactivity in the urine within 5 days with approximately 5.5% in the first 24 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oil Soluble Red PDR**,** Industrial Methylated Spirit

6.2 Incompatibilities

No incompatibilities

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry place below 30^0C; Protect from light

6.5 Nature and contents of container

The primary pack is amber colored bottle. The secondary pack is unit carton made of cardboard.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHPROZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorization Holder

Name: **ASPEN PHARMACARE NIGERIA LIMITED**

Address: **Plot 28, Infinity House, Ilupeju Bypass**

Country: **Nigeria**

Telephone: **+234 90 624 96814**

E-Mail: **info@aspennigeria.com**

Manufacturing Site(s)

Name: **BETA HEALTHCARE INTERNATIONAL LTD**

Address: **Plot No. Nairobi/Block59/135, Mogadishu Road, Industrial Area, Nairobi**

P.O. BOX 42569-00100 Nairobi, Kenya

Country: **KENYA**

Telephone: **+254-20-2652042/89**

E-Mail: info@ke.aspenpharma.com

8. MARKETING AUTHORIZATION NUMBER

NAFDAC REG. No. B4 – 8520

9. DATE OF FIRST REGISTRATION

Date of First Registration: 01 Jul 2018

Date of Renewal of Registration: 18 Nov 2024

10. DATE OF REVISION OF THE TEXT

October 2024

11. DOSIMETRY (IF APPLICABLE)

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable

12. INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable