SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Salisum 25% w/w Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains:
Methyl Salicylate BP …250 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment.
Description: White to off white homogenous ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Salisum is indicated for the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains.

4.2 Posology and method of administration

Posology

Adults and children 2 years and older
Apply externally to the affected area up to 3 to 4 times a day.

Paediatric population under 2 years
To be used as per prescribers advice.

Method of administration
External application. May be applied under occlusive dressing.

4.3 Contraindications

Salisum should not be administered to individuals known to be hypersensitive to methyl salicylate or to any of the components of the formulation, listed in section 6.1.

4.4 Special warnings and precautions for use

Do not apply to broken skin.
Keep out of the sight and reach of children.

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 evidence is available as to the safety of the product when used during pregnancy and lactation. In such cases therefore use with caution.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

This product is recommended for external use only and as such overdose is unlikely. Absorption of methyl alcohol through the skin or ingestion may produce systemic effects. Methyl salicylate may be absorbed through intact skin after excessive topical application.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: NSAIDS, Topical products for joint and muscular pain, ATC code: M02AC

5.1 Pharmacodynamic properties

Methyl salicylate has the action of salicylates, causing dilation of the skin vessels.

5.2 Pharmacokinetic properties

Methyl salicylate is absorbed through the skin.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 3350, polyethylene glycol. 400

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30^{o}C in cool place. Do not freeze. Keep medicine out of reach of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation

30 g of ointment is filled in aluminium tube. Each tube is packed in a carton along with instruction of medical use.

6.6 Special precautions for disposal <and other handling>

None.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.,
SP 289 (A), RIICO Industrial area,
Chopanki, Bhiwadi (Rajasthan), India

8. MARKETING AUTHORISATION NUMBER(S)

07240/09126/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 March 2022

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines