1.3.1.1 PROPOSED PACKAGE INSERT

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

STERKSALF

COMPOSITION

Each 25 g contains:

Methyl salicylate 12,5 g

Excipients:

Beeswax white, woolfat

PHARMACOLOGICAL CLASSIFICATION

A 13.7 Counter-irritants

PHARMACOLOGICAL ACTION

Counter-irritant. The salicylates alleviate pain by virtue of a peripheral action.

INDICATIONS

For backache, lumbago and other muscle and joint pains.

CONTRAINDICATIONS

Sensitivity to methyl salicylate.

DOSAGE AND DIRECTIONS FOR USE

Rub well into affected area twice a day.

FOR EXTERNAL USE ONLY.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Instances of an allergy to methyl salicylate have been reported. In such cases, use must be stopped immediately.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See “Side-effects and Special Precautions”.

IDENTIFICATION

Stiff, pale yellowish ointment.

PRESENTATION

25 g jar with a round flat topped white polypropylene screw-on cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in airtight containers and protect from light

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER

G1509 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Pharmacare Limited

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PACKAGE INSERT

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