1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

GERMOLENE OINTMENT

COMPOSITION

Each 100 g of GERMOLENE OINTMENT contains:

Anhydrous lanolin	38,716 g
Maize starch	7,840 g
Zinc oxide	7,840 g
Methyl salicylate	2,960 g
Phenol	1,184 g
Octaphonium chloride	0,300 g
Menthol	0,012 g

Excipients:

Beeswax white, colour FD & C red (C.I. No. 26100), white soft paraffin

CATEGORY AND CLASS

A 13.1 Antiseptics, disinfectants and cleansing agents

PHARMACOLOGICAL ACTION

GERMOLENE OINTMENT has protective, soothing, analgesic and anti-bacterial properties.

INDICATIONS

GERMOLENE OINTMENT is recommended for abrasions, cuts and scratches, minor burns and scalds, bites and stings, chapped skin and blisters on hands and feet.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

For external use only.

It is dangerous to apply GERMOLENE OINTMENT to the nostrils of infants, it may cause immediate collapse.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Abrasions, cuts and scratches - First wash the area gently with soap and water, and then pat dry. Put GERMOLENE OINTMENT onto lint or an adhesive plaster, and apply. With minor abrasions do not apply a dressing, but rub a little GERMOLENE OINTMENT directly onto the skin.

Minor burns and scalds - As a first aid for burns and scalds, smooth a liberal amount of GERMOLENE OINTMENT onto a piece of lint or a freshly laundered handkerchief, and apply. Anything more serious than a minor burn causing small blisters is a matter for your doctor.

Bites and stings - Apply GERMOLENE OINTMENT to the affected area.

Chapped skin - Apply GERMOLENE OINTMENT after each wash - carefully drying the skin first.

Blisters on hands and feet - Bathe the blistered area in warm water, then pat dry thoroughly and cover the affected area with GERMOLENE OINTMENT.

SIDE EFFECTS

Hypersensitivity to any of the ingredients may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

No risk of overdosage.

Treatment

In the case of accidental ingestion of GERMOLENE OINTMENT, empty the stomach by aspiration and lavage.

Further treatment symptomatic and supportive.

IDENTIFICATION

A smooth ointment, free from grittiness, bubbles and black specks. It has a pink colour and is

uniform, with methyl salicylate/phenol odour.

PRESENTATION

20 g or 50 g is packed in a printed collapsible aluminium tube, with a thick wall cap. The tubes are packed into cardboard cartons.

20 g or 50 g is packed in a laminated tube with a linerless cap. The tubes are packed into cardboard cartons.

Not all packs or pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in a cool dry place.

Keep in original packaging till required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

G1847 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: Old medicine

Date of the most recent amendment to the professional information as approved by the Authority: 18 May 1976

Botswana: B9304600 S4

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