PZ CUSSONS NIGERIA PLC
487 SHAGAMU – IKORODU ROAD. IKORODU
LAGOS, NIGERIA

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) TEMPLATE

ROBB OINTMENT
23ml

1. NAME OF THE MEDICINAL PRODUCT

NAME : ROBB OINTMENT ORIGINAL (23ML)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Camphor 8.0%, Menthol 4%, Methyl Salicylate 4.0%, Eucalyptus Globulus Leaf Oil 1.5%, Pinus Pumilio oil 0.5%.

3. PHARMACEUTICAL FORM

PRODUCT is marketed as a light yellow semi-solid aromatic ointment in PET bottles wrapped with a sleeve and then packaged as 12 units in a secondary packaging.

4. Clinical particulars

Ingredients used in this preparation are recognised globally and their efficiency and safety are well documented.

Please see attached entries from the extra pharmacopeia.

4.1 Therapeutic indications

For relief of muscular aches and pains, nasal congestion, and catarrh.

4.2 Posology and method of administration

For quick relief of catarrh and nasal congestion, apply directly under the nose and not into the nostrils.

For quick relief of muscular aches and pains, apply to parts affected and repeat up to three times per 24 hours or as directed by the doctor.

4.3 Contraindications

NA

4.4 Special warnings and precautions for use

1. Not suitable for children under 12 years of age.
2. Do not swallow or place in nostrils.
3. Keep out of reach of children.
4. Keep away from eyes

4.5Interaction with other medicinal products and other forms of interactions:

Not applicable.

4.6 Pregnancy and lactation:

Not applicable.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

The active ingredients in this preparation, at the prescribed concentrations, pose no risk of side effects.

However, in rare cases, after prolonged use, essential oils and menthol may cause local irritation and dermatitis.

4.9 ANTIDOTE IN THE EVENT OF OVERDOSE

In the event of accidental oral administration, gastric emptying by lavage will suffice. A saline laxative can be administered by mouth e.g. a solution of Sodium Phosphate 30g in 250ml of water.

Convulsions can be controlled by slow I.V. infusion of 5mg to 10mg Diazepam.

4.10
TERATOGENICITY

There is no evidence of teratogenic or mutagenic effects from any of the ingredients used in this preparation.

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5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamics properties

NA

5.1 Pharmacokinetic properties

NA

5.2 Preclinical safety data

Hypersensitivity.

The following adverse reactions can occur if the ointment is taken orally:
Nausea, vomiting, intestinal colic, headache, dizziness, muscle twitching e.t.c.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

S/N	INGREDIENT	FUNCTION
1	Petrolatum	Base, Emollient
2	Paraffin Wax	Thickener
3	CI 47000	Colour
4	CI 26100	Colour

6.2 Incompatibilities

<Not applicable.>

6.3 Shelf life

Shelf life: 3 years

6.4 Special precautions for storage

Store in a cool and dry place not higher than 25 degrees.

6.5 Nature and contents of container <and special equipment for use, administration, orimplantation>

Type of container: PET jars.

Secondary packaging: Nylon Sleeves and Cartons

6.6 Special precautions for disposal <and other handling>

Packaginf materials to be recycled after disposal.

7. <APPLICANT/MANUFACTURER>

PZ CUSONS NIG PLC

< {Tel}> 08074090098

< {Fax}>NA

< {Email}>udoka.adegor@pzcussons.com