

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Brand name: Kapurol

Product name: Camphor and Menthol Gel

Strength: Camphor 3mg, Menthol 3mg

Pharmaceutical: Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration, The active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant

Camphor , Menthol

Quantitative Declaration, The quantity of the active substance must be expressed per dosage unit.

Each gram contains Camphor 3mg and Menthol 3mg

3. PHARMACEUTICAL FORM

Topical Gel

Transparent or semitransparent gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Camphor and Menthol Gel provides soothing relief of minor arthritis pain, aching muscles, joints and backaches.

4.2 Posology/Dosage and method of administration

For external use only.

Adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily and gently massage until gel disappears.

Children under 2 years of age: do not use, consult a doctor.

To use the liquid or stick, uncap the applicator and press it firmly on your skin to apply the medication.

4.3 Contraindication

Avoid contact with eyes or mucous membranes. For arthritis like condition in children under 2, do not use.

4.4 Special warnings and precautions for use

Warnings: For external use only. Use only as directed. Keep out of children to avoid accidental poisoning.

- 1.Avoid contact with eyes or mucous membranes. If this does happen, rinse with water.
- 2.Discontinue use if excessive irritation of the skin develops.
- 3.Do not bandage tightly, apply to wounds, broken or irritated skin, or use with a heating pad.
- 4.If condition worsens, or if symptoms persist for more than 10 days or clear-up and occur again within a few days, if skin redness or irritation develops, discontinue use of this product and consult a doctor.
- 5.For arthritis like condition in children under 12, do not use. Consult a doctor.
- 6.If swallowed, get medical help or contact a Poison Control Center right away.

4.5 Interaction with other drug products and other forms of interaction

Medications known to interact with methyl Muscle Rub: Anisindione, Coumadin (warfarin), Dicumarol, Jantoven (warfarin), Miradon (anisindione), warfarin. But these reports are all drug interactions of methyl salicylate, and there is no adverse interaction between menthol and other drugs.

4.6 Fertility, pregnancy and lactation

It is not known whether Muscle Rub Gel will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medication.

It is not known whether Muscle Rub Gel passes into breast milk or if it could harm a nursing baby. Do not apply Muscle Rub Gel to your breast area if you are breast-feeding a baby.

If pregnant or breast-feeding, ask a health professional before use.

4.7 Effects on ability to drive and use machines

Camphor and Menthol Gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug.

- 1.Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- 2.Skin irritation.
- 3.Redness.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol is a covalent organic compound made synthetically or obtained from peppermint or other mint oils. Menthol's ability to chemically trigger cold-sensitive receptors in the skin is responsible for the well known cooling sensation that it provokes when inhaled, eaten, or applied to the skin. It should be noted that menthol does not cause an actual drop in temperature.

Menthol primarily activates the cold-sensitive TRPM8 receptors in the skin. Menthol, after topical application, causes a feeling of coolness due to stimulation of 'cold' receptors by inhibiting Ca⁺⁺ currents of neuronal membranes. It may also yield analgesic properties via kappa-opioid receptor agonism.

5.2 Pharmacokinetic properties

Menthol has the effect of promoting local circulation and mild antiphlogistic, analgesic and antipruritic effect.

Menthol has a good role in promoting drug penetration, and its mechanism of action is to promote drug absorption through structural changes in the stratum corneum of the skin.

5.3 Preclinical safety data

Topical use of Camphor and Menthol Gel has only rarely been associated with systemic side effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer, Benzyl alcohol, Isopropanol, Trolamine, Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place away from sunlight.

Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Inner-package: Composite Tube.

Pack Size: 85g/tube, 1tube/box

Packaging Specifications (primary packaging, secondary packaging)

Packed in tube in box with 85g and printed with batch number and manufacturing date.

Packed into carton with paper boxed inside.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Applicant: AKSO PHARMACEUTICAL NIGERIA LIMITED..

Adress: No. 320, Odusami Street, off Wempco Road, Ogba , Lagos Nigeria

E-mail: 506798052@qq.com

Contact person : Brian Fu

Tel: 09118269061

8. DRUG PRODUCT MANUFACTURER

Manufacturer name: FRONT PHARMACEUTICAL PLC

Physical address: No.369 Baocheng Road, Xuancheng Economic and Technical Development Zone, Anhui,
China

Tel: 86-0563-2625199

Fax: 86-0563-2625199

E-mail: export@frontpharm.com

9. NAFDAC REGISTRATION NUMBER(S)

