SCHEDULING STATUS
To be allocated.

PROPRIETARY NAME AND DOSAGE FORM
OsteoFreeze® Roll-On (Gel)

COMPOSITION

Active Ingredients	**Per 1 ml gel:**
Menthol Crystals	37 mg
Camphor DAB	2 mg
Arnica spp. Flower Extract	1 mg

Inactive Ingredient: Ethanol (15 % m/m).

PHARMACOLOGICAL CLASSIFICATION
D.3.5 Connective Tissue Medicine – Other.
Combination Western Herbal Medicine.

INDICATIONS
OsteoFreeze® Roll-On contains ingredients that can assist the body with the relief of sore muscles and joints associated with strains, sprains, aches, swelling and stiffness. For a diagnosis or if symptoms persist, consult a medical practitioner. Efficacy of support may vary between users.

CONTRAINDICATIONS
This product is not suitable for children under the age of 10 years. Do not use if a known hypersensitivity or allergy exists towards any of the ingredients. If in doubt consult your medical practitioner.

WARNINGS AND SPECIAL PRECAUTIONS
FOR EXTERNAL USE ONLY. Do not use if a known hypersensitivity or allergy exists towards any of the ingredients. If in doubt consult your medical practitioner. Do not apply the product to damaged or irritated skin. Avoid contact with eyes and mucous membranes. When applied, some individuals might experience a slight stinging or burning sensation. Individuals with thin skin (i.e. the elderly or chronic users of topical corticosteroids) should be cautious when applying OsteoFreeze® Roll-On to their skin. *Arnica* extract may be toxic when used externally on open wounds or for long periods of time. People using anticoagulant - or antiplatelet medication, such as Warfarin, should use this product with caution as *Arnica* may have a blood thinning effect. This product should be used only when clearly needed during pregnancy and lactation (breastfeeding). Discuss the risks and benefits with your medical practitioner. Do not exceed the recommended daily application dosage. Do not use after date of expiry. Check expiry date on unit. Products containing herbal ingredients may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.
Porphyria: Safety has not been established.
KEEP OUT OF REACH OF CHILDREN.

INTERACTIONS
Products containing herbal ingredients may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner. People using anticoagulant - or antiplatelet medication, such as Warfarin, should use this product with caution as *Arnica* may have a blood thinning effect.

PREGNANCY AND LACTATION
This product should be used only when clearly needed during pregnancy and lactation (breastfeeding). Discuss the risks and benefits with your medical practitioner.

DOSAGE AND DIRECTIONS FOR USE
FOR EXTERNAL USE ONLY.
Do not exceed the recommended daily application dosage.
Adults and children 10 years and older:
Apply a thin layer to the affected area 3-4 times a day. Wash hands with soap and warm water after application, or wear gloves when applying the product. Do not apply the product to damaged or irritated skin.

SIDE EFFECTS
If you experience any side effects or sensitivity towards any of the ingredients, discontinue use. If symptoms persist, or if any adverse reactions occur, consult a medical practitioner. Side effects may include, but are not limited to; stinging -, burning - or itching sensations.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Do not exceed the recommended daily application dosage. If any irritation occurs, please consult a medical practitioner. Symptoms may include, but are not limited to; oedematous dermatitis, local burning, itching and stinging. Treatment is symptomatic and supportive.
If accidentally ingested, do not induce vomiting. Drink lots of water and consult a medical practitioner. If accidental eye contact occurs, rinse with cold water or milk and consult a medical practitioner.

IDENTIFICATION
Transparent gel.

PRESENTATION
50 ml roll-on applicator, in a unit carton, with a package insert.

STORAGE INSTRUCTIONS
Store below 25 °C. Store away from direct sunlight.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
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DATE OF PUBLICATION OF THE PACKAGE INSERT
July 2004

This medicine has not been evaluated by the Medicines Control Council.
This medicine is not intended to diagnose, treat, cure or prevent any disease.