

KINESYS ANALGESIC SPORT- methyl salicylate and menthol stick
Wilc Healthcare Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Analgesic Sport Stick

RECOMMENDED USE

Temporarily relieves aches and pains of muscles and joints associated with one or more of the following: backache, strains and sprains (involving muscles, tendons, and/or ligaments), and arthritis.

DURATION OF USE

Consult a health care practitioner for use beyond 7 days.

- Store protected from direct light and moisture at room temperature.

MEDICINAL INGREDIENTS (PER DOSE UNIT)

Methyl salicylate 30%, Menthol (l-Menthol, Mentha arvensis - Herb top) 15%.

NON-MEDICINAL INGREDIENTS

Propylene glycol, PEG-8, Ethyl alcohol, Sodium stearate, Aqua, D&C Green No. 5.

RECOMMENDED DOSE

Adults, adolescents

1-4 time(s) per day. Apply thinly and evenly to affected area up to 3 to 4 times per day. Rub and/or massage into skin until solution vanishes. For external use only. Avoid contact with the eyes and mucous membranes. Do not apply to wounds or damaged skin. Do not tightly bandage. Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn.

Children 2-12 years old

1-4 time(s) per day. Application should be supervised by an adult. Apply thinly and evenly to affected area up to 3 to 4 times per day. Rub and/or massage into skin until solution vanishes. For external use only. Avoid contact with the eyes and mucous membranes. Do not apply to wounds or damaged skin. Do not tightly bandage. Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn.

CAUTIONS AND WARNINGS

Keep out of the reach of children.

If overdose or accidental ingestion occurs, call a Poison Control Center immediately.

Discontinue use and consult a health care practitioner if symptoms persist and/or worsen after 7 days or re-occur within a few days.

Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding .

Consult a healthcare practitioner prior to use if you are taking anticoagulant medications.

Store protected from direct light and moisture at room temperature.

KNOWN ADVERSE REACTIONS

Rashes and/or burning discomfort have been known to occur; in which case, discontinue use.
Hypersensitivity such as allergy has been known to occur; in which case, discontinue use.

PRINCIPAL DISPLAY PANEL - 50 g Cylinder Label

KINeSYS®

Analgesic

SPORT STICK

- *penetrating warm **PAIN RELIEF**
for muscular and arthritic discomfort*

*extra strength **MUSCLE CARE***

Topical

Hands-free applicator

50 g (1.76 OZ)

NPN 80029329



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USAGE RECOMMANDÉ : Soulager temporairement les courbatures et les douleurs des muscles et des articulations associés à l'un des troubles suivants : maux de dos, foulures, entorses (touchant les muscles, les tendons et/ou les ligaments) et arthrite.

DURÉE D'UTILISATION : Consulter un professionnel de la santé avant d'utiliser ce produit plus de 7 jours consécutifs.

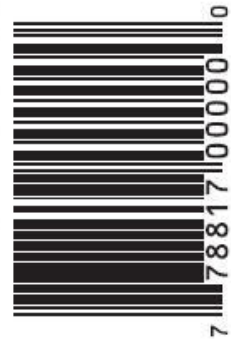
• Ranger dans un endroit à température ambiante à l'abri de la lumière directe et de l'humidité.

INGRÉDIENTS MÉDICINAUX (PAR UNITÉ POSOLOGIQUE) : Salicylate de méthyle 30 %, Menthol (l-Menthol, Mentha arvensis - partie supérieure de la plante) 15 %.

INGRÉDIENTS NON MÉDICINAUX : Propylène glycol, PEG-8, Alcool éthylique, Stéarate de sodium, Aqua, Colorant D&C vert no 5.

KINeSYS Pharmaceutical Inc.
V6V 2L9, Canada

1-888-KINeSYS / www.kinesys.ca
Product of Canada / Produit du Canada



DOSE RECOMMANDÉE :

Adultes, adolescents : 1 à 4 applications par jour. Appliquer une couche mince et uniforme sur la zone affectée jusqu'à 3 ou 4 fois par jour. Frotter et/ou masser la peau jusqu'à ce le produit disparaisse. Pour usage externe seulement. Éviter le contact avec les yeux et les muqueuses. Ne pas appliquer sur des blessures ouvertes ou sur la peau endommagée. Ne pas trop serrer le bandage sur la zone affectée. Ne pas appliquer avec une source de chaleur externe, comme un coussin chauffant électrique, car cela peut causer de l'irritation ou des brûlures.

Enfants entre 2 et 12 ans : 1 à 4 applications par jour. Un adulte doit superviser l'application. Appliquer une couche mince et uniforme sur la zone affectée jusqu'à 3 ou 4 fois par jour. Frotter et/ou masser la peau jusqu'à ce le produit disparaisse. Pour usage externe seulement. Éviter le contact avec les yeux et les muqueuses. Ne pas appliquer sur des blessures ouvertes ou sur la peau endommagée. Ne pas trop serrer le bandage sur la zone affectée. Ne pas appliquer avec une source de chaleur externe, comme un coussin chauffant électrique, car cela peut causer de l'irritation ou des brûlures.

PRÉCAUTIONS ET MISES EN GARDE :

Tenir hors de portée des enfants. En cas de surdose ou d'ingestion accidentelle, appeler un centre anti-poison immédiatement. Cesser d'utiliser ce produit et consulter un professionnel de la santé si les symptômes persistent ou s'aggravent dans les 7 jours ou réapparaissent après quelques jours. Consulter un professionnel de la santé avant d'utiliser ce produit si vous êtes enceinte ou si vous allaitez. Consulter un professionnel de la santé avant d'utiliser ce produit si vous prenez des anticoagulants. Ranger dans un endroit à température ambiante à l'abri de la lumière directe et de l'humidité.

RÉACTIONS INDÉSIRABLES CONNUES :

Ce produit a été reconnu pour causer parfois des éruptions cutanées et/ou des sensations de brûlure; cesser d'utiliser le produit en cas de problème. Ce produit a été reconnu pour provoquer parfois de l'hypersensibilité, comme des allergies; cesser d'utiliser le produit en cas de problème.

STOP-ARRÊT

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61481-00-20
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
WATER (UNII: 059QF0KO0R)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61481-0020-1	50 g in 1 CYLINDER; Type 0: Not a Combination Product	05/31/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	05/31/2012	

Labeler - Wilc Healthcare Inc (203499140)**Registrant** - Wilc Healthcare Inc (203499140)**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmeceutical Research Laboratory Inc		256797309	manufacture(61481-0020)

Revised: 9/2019

Wilc Healthcare Inc