OPITOX TOPICAL GEL- menthol camphor gel Vivera Pharmaceuticals, 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.

OPITOX TOPICAL GEL PAIN RELIEF

DRUG FACTS

Active Ingredients

Menthol 3.5% Camphor 0.2%

Purpose

MentholTopical Analgesic CamphorTopical Analgesic

Uses: For temporary relief of minor aches and pains of sore muscles and joints associated with:

- arthritis
- backache
- strains
- sprains

Warnings: For external use only.

Flammable: Keep away from excessive heat or open flame.

Ask a doctor before use if you have: Sensitive skin

When using this product: Avoid contact with the eyes and/or mucous membranes; Not for ophthalmic use; Do not apply to wounds or damaged skin; Do not use with other sprays, ointments, creams or liniments; Do not apply to irritated skin or if excessive irritation develops; Do not bandage; Do not use with heating pads or device.

Stop use and contact your physician if:

Condition worsens, irritation develops, or if symptoms persist for more than seven (7) days, or clear up and recur.

Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

If pregnant or breast-feeding: Ask a health professional before use.

Directions:

Adults and Children 12 years of age and older: Rub a thin film over affected area(s) not more than four (4) times daily. Rinse hands with cool water after use. Use only as directed.

Children under 12 years of age: Consult physician

OTHER INFORMATION: Store in a cool, dry place with lid closed tightly.

Inactive Ingredients: SD Alcohol 40-B, Water, Carbomer, Glycerin, Cannabis Sativa (Hemp) Seed Oil, Cannabidiol (CBD), Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Mentha Piperita (Peppermint) Oil, Mentha Viridis (Spearmint) Leaf Oil, Propylene Glycol, Hamamelis Virginiana (Witch Hazel) Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Capsicum Annuum Fruit Extract, Camellia Sinensis (Green Tea) Leaf Extract, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Triethanolamine

Questions or Comments: 1-844-484-8372

Principal Display Package

NDC# 72380-521-10

soba[®] medical

OPITOX[®] TOPICAL GEL

PAIN RELIEF

BOX CONTAINS: 3 FL OZ (88.7mL) TOPICAL GEL

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SUGGESTED USE: Adults and Children 12 years of age and older: Rub a thin film over affected area(s) not more than four (4) times daily. Rinse hands with cool water after use. Use only as directed. Children under 12 years of age: Consult physician.

WARNINGS: Do not exceed suggested use. This product is not intended for pregnant or lactating mothers. All individuals should consult with a health practitioner prior to use. If you experience any adverse reactions after use, please discontinue and consult your doctor. Keep out of reach of children. Not for ophthalmic use.

soba[®] medical

Manufactured for: Soba Medical A subsidiary of Vivera Pharmaceuticals 11100 Greenstone Ave. Santa Fe Springs, CA 90670 www.opitox.com MADE IN USA REV11202019

soba[®] medical

OPITOX[®] TOPICAL GEL

<u>Retail Box</u>



<u>Tube</u>

NDC# 72380-521-10



Drug Facts	
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Camphor 0.2%	
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Stop use and contact your physician irritation develops, or if symptoms persist or clear up and recur.	n if: Condition worsens, for more than seven (7) days,
Keep out of reach of children: If accid help or contact a Poison Control Center im	dentally ingested, get medical mediately.
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Questions or Comments: 1-844-484-8	0.070

REV11192019

Manufactured for: Soba Medical A subsidiary of Vivera Pharmaceuticals 11100 Greenstone Ave. Santa Fe Springs, CA 90670 www.opitox.com



Information Insert

NAME AND STRENGTH OF ACTIVE SUBSTANCE lonthe 3.5%

PRODUCT DESCRIPTION The OPITOX* Get is complised of the topical analysis, menthol, and campter.

PHARMACODYNAMICS

Camphor is a stimulant, rubefacient, antipruttic, and an antiseptic When in combination with other ingrecients live menthol, it becames ideal for neuralgia and other painful areas.

which I Membral distes the blood vessels causing a ternation of osidness, bibweel by an anaigosic effect. Narmol also acts as a penetration enhances, increasing the penetration of drugs when applied on the skin, to give a factor close of actor.

PHARMACORINETICS

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urine. • Camphor crosses the placerra.

Menthol After absorption, menthol is excreted in the unne and bile as a glucuronide.

INDICATION TOUCH

cora anaporo: - Powdee grantomatic relief for mid-to moderate muscular and joint aches and pains, muscle cramps, shoulder arbits and stiff neck. - Far the temporary relief of pain associated with thermitters, anthros, neuraigia, sprains and strains of joints and muscles, luminage and formatis.

CRIMINING DOSAGE
Gel - Jahls and Children 17 years of age and older
- Sita a tim fine over their dat activity in the rest that four (1) times doly,
- take every 4 to 6 hours. Wath hands with cost water after each use.
- Far estimal application only.
- Children under 12 years of age, consult physician.

MODE OF ADMINISTRATION Traveal analogoit

CONTRAINDICATIONS

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Drug Facts	
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Dentitive or Conventer 1 018-438-0	272



NDC#72380-521-10





ARNINGS AND PRECAUTIONS (CONTINUED)

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INTERACTIONS WITH OTHER MEDICAMENTS

NON NOWN. STATEMENT ON USAGE DURING PREGNANCY AND LACTATION If program or treast-feeding: Ask a health professional belt

nant or breast-feeding: Ask a health professional before use.

ADVERSE EFFECTS / UNDESIRABLE EFFECTS

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OVERDOSE AND TREATMENT workdowe who instrumentation
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including severe abdominal pain, nausea, vomiting, verligo, atavia, drowsiness, and coma; instant collapse in infants after the

local application of mentholicamphor to their nozvits. Secure may be the test dimical sign of servers testory of camphor, however, solarizers are usually self-initial. Beard toxicity of camphor can result in definiting, usuall'habitomations encrearie defined, and status a planeticus. Systemic toxicity may include hypotension, lashystardia, respiratory tafure, and deal

Include representation, exception and an employed and a second a seco

In case of consumption seek professional assistance or contact a Poison Control Center Immediately.

Poison Contrait Centriar Immediately. \$105ABCE CONDITIONS Strar en cost, dry phone with Gir chare dipley. DOSAGE FORMS AND PACKAGING ANANLABLE - 31 or (031 ms), where the affected areas not more than loss (4) times daily. Rinse hands with cost waiter also.

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER Sola Menol A satisfield A satisfield of the Pharmateuticals, (nc. 1910) Greenotice due Solar & Springs, CA. 90670. DATE OF REVISION OF PACKAGE INSERT: 11272019







Manufactured For. Soba Medica? Soba Medica? A subsidiary of Vivera Pharmaceutica's 11000 Greenstone Ave. Santa Fe Springs, CA 90670 www.Opticx.com



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nenthol camphor gel					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Sour	ce) NDC	NDC:72380-521	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
	Ingredient Name		Basis of Streng	th Strength	
				3.5 g	
MENTHOL (UNII: L7T10EIP3A) (N	MENTHOL - UNII:L7T10EIP3A)		MENTHOL	in 100 mL	
CAMPHOR (SYNTHETIC) (UNII:		HETIC) -	MENTHOL CAMPHOR (SYNTHETIC)		
CAMPHOR (SYNTHETIC) (UNII:		HETIC) -	CAMPHOR	in 100 mL 0.2 g	
MENTHOL (UNII: L7T10EIP3A) (N CAMPHOR (SYNTHETIC) (UNII: UNII:5TJD82A1ET) Inactive Ingredients		ΉΕΤΙC) -	CAMPHOR	in 100 mL 0.2 g	

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CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)						
GLYCERIN (UNII: PDC6A3C0OX)						
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)						
CANNABIDIOL (UNII: 19GBJ60SN5)						
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)						
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)						
PEPPERMINT OIL (UNII: AV092KU4JH)						
SPEARMINT OIL (UNII: C3M81465G5)						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)						
TEA TREE OIL (UNII: VIF565UC2G) PADDIK A (UNII: X72747861V)						
PAPRIKA (UNII: X72Z47861V)						
GREEN TEA LEAF (UNII: W2ZU1RY8B0) PHENOXYETHANOL (UNII: HIE492ZZ3T)						
CAPRYLIC ALCOHOL (UNII: NV1779205D)						
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)						
HEXYLENE GLYCOL (UNII: KEH0A3F75J) TROLAMINE (UNII: 903K93S3TK)						
TROLAMINE (ONI. 905R9555TR)						
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:72380-521-10	1 in 1 BOX	08/06/2019				
1	88.7 mL in 1 TUBE; Type 0: Not a Combination Product					
Marketing Information						
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	08/06/2019				

Labeler - Vivera Pharmaceuticals, Inc. (081244342)

Revised: 12/2019

Vivera Pharmaceuticals, Inc.