

**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.*

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**OPITOX TOPICAL GEL PAIN RELIEF**

**DRUG FACTS**

***Active Ingredients***

Menthol 3.5%

Camphor 0.2%

***Purpose***

Menthol .....Topical Analgesic

Camphor .....Topical 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 Annum 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**<sup>®</sup>  
medical

**OPITOX**<sup>®</sup>  
TOPICAL GEL

**PAIN RELIEF**

**BOX CONTAINS:**

3 FL OZ (88.7mL)

TOPICAL GEL

6 16728 00059 0

### **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**<sup>®</sup>  
medical

Manufactured for:

Soba Medical

A subsidiary of Vivera Pharmaceuticals

11100 Greenstone Ave. Santa Fe Springs, CA 90670

[www.opitox.com](http://www.opitox.com)

MADE IN USA REV11202019

**soba**<sup>®</sup>  
medical

**OPITOX**<sup>®</sup>  
TOPICAL GEL

Retail Box



NDC# 72390-521-10

sobar  
 medical

sobar  
 medical

**Drug Facts**

Active Ingredients	Purpose
Menthol 3.5%	Topical Analgesic
Camphor 0.2%	Topical 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 topical drugs, ointments, creams or liniments; Do not apply to irritated skin or if an adverse irritation develops; Do not bandage; Do not use with heating pads or darts.

**Stop use and contact your physician if:** Condition worsens, irritation develops, or if symptoms persist for more than seven (7) days, or do not get better.

**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, Camellia Salsa (Hemp) Seed Oil, Carnauba Wax (C80), Aloe Barbadensis Leaf Juice, Anise Maritima Flower Extract, Mentha Piperita (Peppermint) Oil, Mentha Viridis (Spearmint) Leaf Oil, Propylene Glycol, Hamamelis Virginiana (Witch Hazel) Extract, Mikaleuca Alternifolia (Tutu 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

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 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.



**PAIN RELIEF**

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

Manufactured for:  
 Sobar Medical  
 A subsidiary of Viversa Pharmaceuticals  
 11100 Greentown Ave.  
 Santa Fe Springs, CA 90670  
[www.opitox.com](http://www.opitox.com)



RBV11202019



Tube

NDC# 72380-521-10

soba<sup>®</sup>  
medical



**PAIN RELIEF**

3.0 FL OZ (88.7 mL)

**Drug Facts**

Active Ingredients	Purpose
Menthol 3.5%	Topical Analgesic
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**Questions or Comments:** 1-844-484-8372

REV11192019

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



Information Insert



CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
GLYCERIN (UNII: PDC6A3C0OX)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)
CANNABIDIOL (UNII: 19GBJ60SN5)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
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)
PAPRIKA (UNII: X72Z47861V)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLIC ALCOHOL (UNII: NV1779205D)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
TROLAMINE (UNII: 9O3K93S3TK)

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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/06/2019	

**Labeler** - Viverra Pharmaceuticals, Inc. (081244342)