

TVIA 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.

TVIA GEL

DRUG FACTS

ACTIVE INGREDIENTS

Menthol 3.5%

Camphor 0.2%

PURPOSE

MentholTopical Analgesic

CamphorTopical Analgesic

USES: For temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis pain • 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 • Do not use with other sprays, ointments, creams or liniments • Do not apply to irritated skin, & discontinue use if excessive skin irritation develops • Do not bandage • Do not use with heating pads or device.

Stop use and contact your physician if: conditions worsen, or if symptoms persist for more than seven (7) days, or clear up and reoccur.

If pregnant or breast-feeding: Ask a health professional before use. Children under 2 years of age: Consult physician

KEEP OUT OF REACH OF CHILDREN: If swallowed, get medical help or contact a poison control center immediately

DIRECTIONS: Use only as directed. Rub a thin film over the affected areas not more than four (4) times daily. Rinse hands after use with cool water.

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

INACTIVE INGREDIENTS: Ethyl Alcohol Denatured, Deionized Water, Glycerin, Propylene Glycol, Cannabis Sativa Seed Oil (Hemp Seed Oil), Cannabidiol (CBD), Arnica Montana Flower Extract (Arnica Oil), Mentha Piperita (Peppermint) Oil, Carbomer, Triethanolamine, Mentha Viridis (Spearmint) Leaf Oil, Camellia Sinensis Leaf Extract, Aloe

Barbadensis Leaf Extract, Hamamelis Virginiana (Witch Hazel) Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil,

Principal Display Package

NDC# 72380-728-10

**VIVERA®
PHARMACEUTICALS**

**TVIA GEL®
T O P I C A L G E L**

PAIN RELIEF

BOX CONTAINS:

3 FL OZ (88.7mL)

TOPICAL GEL

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**TVIA GEL®
T O P I C A L G E L**

SUGGESTED USE: Apply a small amount topically to affected area and rub in. Use every 4 to 6 hours. Safe for use on adults over 21 years of age. Wash hands with cool water after each use.

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. This product has not been evaluated by the Food and Drug Administration.

**VIVERA®
PHARMACEUTICALS**

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

VIV-71000-GBX REV20190115

**VIVERA®
PHARMACEUTICALS**

Manufactured For:
Viverra Pharmaceuticals, Inc.
11100 Greenstone Ave
Santa Fe Springs, CA 90670

MADE IN USA

Retail Box

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 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 devices.

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, Cassia Seed Oil, Sesame 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, Melissa Leuca Adhumbata (Tea Tree) Leaf Oil, Capsicum Annuum Fruit Extract, Cannabis Sinensis (Brikan Tea) Leaf Extract, Phenylethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Thiodiolamine

Questions or Comments: 1-844-484-8372



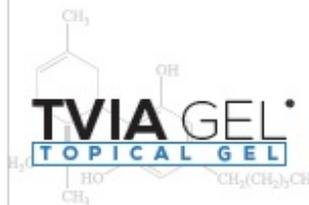
REV1 1202019

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

NDC# 72380-728-10



PAIN RELIEF

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

Manufactured For:
Vivera Pharmaceuticals, Inc.
11100 Greenstone Ave
Santa Fe Springs, CA 90670



Tube

NDC# 72380-728-10



PANTONE RED 032



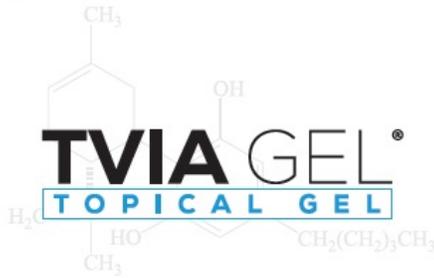
PANTONE 2925C



BLACK



GREY



PAIN RELIEF

3.0 FL OZ (88.7 mL)

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: <ul style="list-style-type: none"> • 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, Phenoxethylalcohol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Triethanolamine	
Questions or Comments: 1-844-484-8372	

REV11192019

Manufactured For:
Vivera Pharmaceuticals, Inc.
11100 Greenstone Ave
Santa Fe Springs, CA 90670



Insert

NAME AND STRENGTH OF ACTIVE SUBSTANCE
 Menthol 3.5%
 Camphor 0.2%

PRODUCT DESCRIPTION
 The TVIA® Gel is comprised of the topical analgesic, menthol, and camphor.

PHARMACODYNAMICS

Camphor
 • Camphor is a stimulant, rubefacient, antipruritic and an antiseptic. When in combination with other ingredients like menthol, it becomes ideal for neuralgia and other painful areas.

Menthol
 • Menthol dilates the blood vessels causing a sensation of coldness, followed by an analgesic effect. Menthol also acts as a penetration enhancer, increasing the penetration of drugs when applied on the skin, to give a faster onset of action.

PHARMACOKINETICS

Camphor
 • Camphor is readily absorbed from all administration sites. Camphor is well absorbed after dermal exposure.
 • It is hydroxylated in the liver to yield hydroxycamphor metabolites which are then conjugated with glucuronic acid and excreted in the urine.
 • Camphor crosses the placenta.

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

INDICATION

Topical analgesic
 • Provide symptomatic relief for mild to moderate muscular and joint aches and pains, muscle cramps, shoulder aches and stiff neck
 • For the temporary relief of pain associated with rheumatism, arthritis, neuralgia, sprains and strains of joints and muscles, lumbago and fibrositis

RECOMMENDED DOSAGE

Gel - Adults and Children 12 years of age and older
 • Rub a thin film over affected area(s) not more than four (4) times daily.
 • Use every 4 to 6 hours. Wash hands with cool water after each use.
 • Rub/Massage gently
 • For external application only
 • Children under 12 years of age: Consult physician

MODE OF ADMINISTRATION

Topical analgesic

CONTRAINDICATIONS

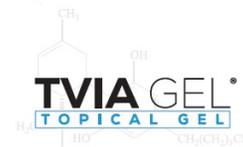
• Do not use in patients with aspirin or salicylate idiosyncrasy.
 • Hypersensitivity to any of the ingredients in the product.
 • Product can cause convulsions.
 • Avoid direct application into nostrils
 • Not for ophthalmic use.

WARNINGS AND PRECAUTIONS

WARNING:
 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. Do not use with other sprays, ointments, creams or liniments. Do not apply to irritated skin, and discontinued use if excessive skin irritation develops. Do not bandage. Do not use heating pads or device.



NDC# 72380-728-10



TVIA GEL®
TOPICAL GEL

PAIN RELIEF



Vivera Pharmaceuticals, Inc.
 11100 Greenstone Ave.
 Santa Fe Springs, CA 90670
 www.ViveraPharma.com

WARNINGS AND PRECAUTIONS (CONTINUED)

For external use only, (continued)
 • Stop use and contact your physician if: conditions worsen, or if symptoms persist for more than seven (7) days, or clean up and recur.
 • If pregnant or breast-feeding: Ask a health professional before use.
 • Children under 12 years of age: Consult physician.
 • **KEEP OUT OF THE REACH OF CHILDREN:** If swallowed, get medical help or contact a poison control center immediately.
 • 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 children. This product has not been evaluated by the Food and Drug Administration.

INTERACTIONS WITH OTHER MEDICATIONS

None known

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION

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

ADVERSE EFFECTS / UNDESIRABLE EFFECTS

• This product can cause convulsions.
 • Headache, dizziness, nausea and vomiting, skin irritation, contact dermatitis, rash, itching, redness or swelling, burning or stinging sensation may occur.
 • May cause hypersensitivity/allergic reactions in some individuals with sensitive skin

OVERDOSE AND TREATMENT

Symptoms of camphor/menthol overdose
 • For external use only
 • Ingestion of significant quantities is reported to cause symptoms including severe abdominal pain, nausea, vomiting, vertigo,

ataxia, drowsiness, and coma; instant collapse in infants after the local application of menthol/camphor to their nostrils.
 • Seizures may be the first clinical sign of severe toxicity of camphor; however, seizures are usually self-limited. Severe toxicity of camphor can result in delirium, visual hallucinations, cerebral edema, and status epilepticus. Systemic toxicity may include hypotension, tachycardia, respiratory failure, and death.

Treatment

• The stomach should be emptied by gastric lavage or administration of oral activated charcoal
 • Fluid and electrolyte management is the mainstay of treatment with the immediate aim of correction of acidosis, hyperpyrexia, hypokalaemia and dehydration if present.
 • Any convulsions must be controlled first through supportive care including anticonvulsant therapy

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

STORAGE CONDITIONS

Store in a cool, dry place with lid close tightly.

DOSAGE FORMS AND PACKAGING AVAILABLE

• 38 oz (88.7mL)
 • Rub a thin film over the affected areas not more than four (4) times daily. Rinse hands with cool water after use

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

Vivera Pharmaceuticals, Inc.
 11100 Greenstone Ave.
 Santa Fe Springs, CA 90670.

DATE OF REVISION OF PACKAGE INSERT: 11202019



Manufactured For:
 Vivera Pharmaceuticals, Inc.
 11100 Greenstone Ave.
 Santa Fe Springs, CA 90670
 www.ViveraPharma.com



TVIA Topical Gel by Vivera Pharmaceuticals, Inc.

res

TVIA TOPICAL GEL

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72380-728
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)
CANNABIDIOL (UNII: 19GBJ60SN5)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
PEPPERMINT OIL (UNII: AV092KU4JH)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
TROLAMINE (UNII: 9O3K93S3TK)
SPEARMINT OIL (UNII: C3M81465G5)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
HAMAMELIS VIRGINIANA LEAF WATER (UNII: 8FP93ED6H2)
TEA TREE OIL (UNII: VIF565UC2G)
PAPRIKA (UNII: X72Z47861V)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAPRYLIC ALCOHOL (UNII: NV1779205D)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72380-728-10	1 in 1 BOX	12/01/2018	
1		88.7 mL in 1 PACKET; 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	12/01/2018	

Labeler - Vivera Pharmaceuticals, Inc. (081244342)

Revised: 12/2019

Vivera Pharmaceuticals, Inc.