TUVIVEX10- menthol, unspecified form cream
Tuvive Therapeutics

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.

Tuvīvex™10

Drug Facts

Active Ingredient

Menthol 4%

Purpose

Topical Analgesic

Uses

Aid for temporary local relief of minor pain in muscles or joints.

Warnings

- **For external use only.**
- Avoid contact with eyes.
- Do not apply to wounds or damaged skin.
- If symptoms persist for more than seven days, discontinue use and consult a physician.

IF PREGNANT OR BREASTFEEDING

Ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

If swallowed, get medical help right away.

Directions

Adults and children two years of age or older:

- Apply to affected area not more than three to four times daily.
- Children under two years of age, consult a physician.

Additional Information

Store in a cool, dry place at 20 to 25 C (68 to77 F) with lid closed tightly.

Inactive Ingredients

Aqua, Emu Oil, Alcohol Denat., Stearic Acid, Glycerin, Glyceryl Stearate, Caprylic/Capric Triglyceride, Cetyl Alcohol, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol, Squalane, Stearyl Alcohol, Hemp-Derived Cannabidiol (CBD), Sodium Hydroxide, Aloe Barbadensis Leaf Extract, Boswellia Serrata Extract, Arnica Montana Flower Extract.

To report a serious adverse event or to obtain product information, contact Company number at 1-844-720-7251

PRINCIPAL DISPLAY PANEL - 100 mL Bottle Label

Tuvīve
Therapeutics

73501-501-10

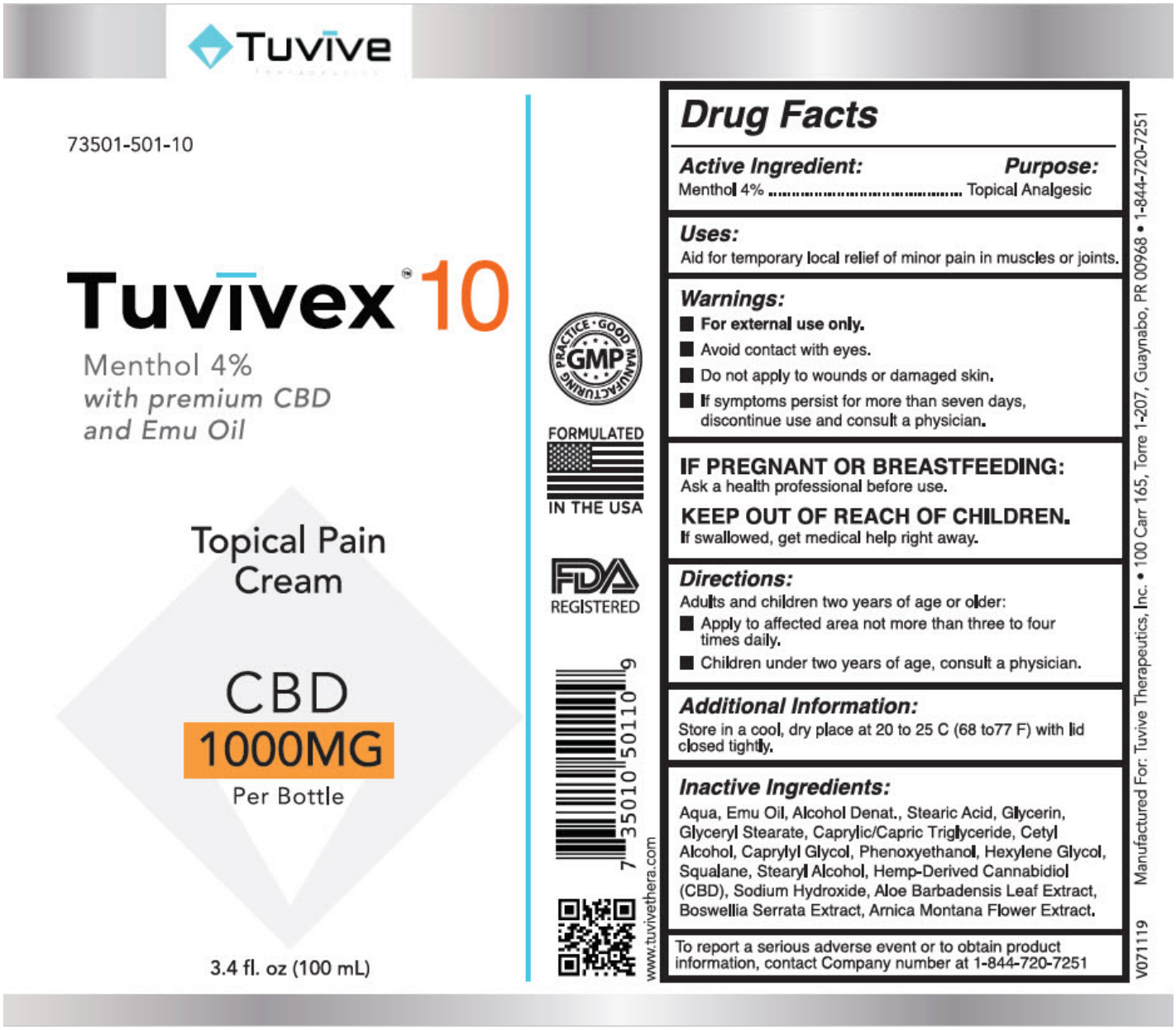
Tuvīvex™ 10

Menthol 4%
with premium CBD
and Emu Oil

Topical Pain
Cream

CBD
1000MG
Per Bottle

3.4 fl. oz (100 mL)



TUVIVEX10

menthol, unspecified form cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73501-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Emu Oil (UNII: 344821WD61)	
ALCOHOL (UNII: 3K9958V90M)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Glycerin (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Squalane (UNII: GW89575KF9)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
Sodium Hydroxide (UNII: 55X04QC32I)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73501-501-10	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/10/2020	

Labeler - Tuvive Therapeutics (117298967)

Revised: 1/2022 Tuvive Therapeutics