TUVIVEX- menthol, unspecified form gel
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™

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 ptace at 20 to 25 C (68 to77 F) with lid closed tightly.

Inactive Ingredients

Aqua, Alcohol Denat, Steareth-21, Glycerin, Caprylyl Glycol, Phenoxyethanol, Hexylene Glycol, Hemp-Derived Cannabidiol (CBD), Arnica Montana Flower Extract, Steareth-2, Cetyl Alcohol, Xanthan Gum, Boswellia Serrata Extract.

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

PRINCIPAL DISPLAY PANEL - 90 mL Bottle Label

Tuvīve
Therapeutics

73501-500-90

Tuvīvex™
Menthol 4% Roll on Gel
with CBD

Roll On
Pain Gel

CBD
500MG
Per Bottle

3 fl. oz (90 mL)

TUVIVEX

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73501-500
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)	
ALCOHOL (UNII: 3K9958V90M)	
Steareth-21 (UNII: 53J3F32P58)	
Glycerin (UNII: PDC6A3C0OX)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Hexylene Glycol (UNII: KEH0A3F75J)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
Steareth-2 (UNII: V56DFE46J5)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Xanthan Gum (UNII: TTV12P4NEE)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73501-500-90	90 mL in 1 BOTTLE, WITH APPLICATOR; 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