

TRUU BALANCE PAIN RELIEF- lidocaine hydrochloride and menthol, unspecified form cream

Philia Group LLC

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.

Truu Balance Pain Relief

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Lidocaine 4% HCl w/w	External Analgesic
Menthol 1% w/w	External Analgesic

Uses

For temporary relief of pain, burning, or itching where applied locally

Warnings

For external use only

Avoid contact with eyes

Do not use in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask Doctor if

- Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

- If product is swallowed get medical help or contact a Poison Control Center right away.
- This product is not intended to diagnose, treat, cure or prevent any disease

Directions

Apply in a circular motion for 30 to 60 seconds

For adults and children two-years and older: apply to affected area not more than 3 to 4 times daily.
Children under 2 years of age: consult a physician.

Inactive ingredients

Aqua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine, Full Spectrum Hemp Extract. (Aerial Parts)

Other Information

Protect this product from excessive heat and direct sunlight

Questions or Comments

FDA Registered: NDC No. _____-____-____

Distributed by Philia Group LLC

Address: 4 Flanders Drive, Pine Brook, NJ 07058

PRINCIPAL DISPLAY PANEL - 113 g Bottle Label

Truu
Balance

Pain Relief Cream
Organic Full Spectrum CBD
With lidocaine

THIRD PARTY
LAB TESTED

1000mg CBD
4oz | 113g

Powered By
pilot™
World's Best Driver

Truu Balance

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Distributed by Philia Group LLC | Website: www.truubalance.com
Address: 4 Flanders Drive, Pine Brook, NJ 07058 | Phone: (800) 298-0667

TRUU BALANCE PAIN RELIEF

lidocaine hydrochloride and menthol, unspecified form cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73596-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4000 mg in 113 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1000 mg in 113 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73596-100-01	1 in 1 BOX	08/17/2020	
1		113 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/17/2020	

Labeler - Philia Group LLC (117363263)

Establishment			
Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		171837367	MANUFACTURE(73596-100)

Revised: 8/2020

Philia Group LLC