# TIDL PAIN RELIEF MASSAGING ROLL-ON- roll-on liniment The Anthos Group

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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## 79740-011 TIDL PAIN RELIEF MASSAGING ROLL-ON

Lidocaine 4%,

Menthol 2.5%

Topical anesthetic

Use for the temporary relief of pain

Wamings

For external use only.

If pregnant or breast-feeding , ask a health professional before use . Keep out of reach of children and pets. If swallowed , get medical help or contact a Poison Control Center right away

Ginger Extract
Saffron Extract
Water
Mugwort Leaf Extract
Vanillyn Butyl
Borneol
Carbohydrates

#### **Directions**

Adults and children 12 years of age and older apply a thin layer to affected area every 6-8 hours , not more han 3-4 times daily massage until thoroughly absorbed into skin wash hands with soap and water after each usemore than 3 to 4 times daily Children under 12 years of age : consult a doctor

79740-011-01





79740-011-02





### **TIDL PAIN RELIEF MASSAGING ROLL-ON**

roll-on liniment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79740-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
SIALYL LEWIS A (UNII: ZEJ6FM4UJK)			
GINGER (UNII: C5529G5JPQ)			
CROCUS SATIVUS FLOWER (UNII: 00IF91KFKQ)			
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)			
ETHYL VANILLIN (UNII: YC9ST449YJ)			
WATER (UNII: 059QF0KO0R)			

DODNEOL	/I INIII.	M89NIB437X	Α.
DURINEUL	TOINII.	141021111D42/V	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79740-011- 02	85 g in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2022	
2	NDC:79740-011- 01	85 g in 1 BOTTLE; Type 0: Not a Combination Product	10/26/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/26/2022	

### Labeler - The Anthos Group (117511051)

Establishment				
Name	Address	ID/FEI	Business Operations	
THE ANTHOS GROUP		117511051	manufacture(79740-011)	

Revised: 10/2022 The Anthos Group