WELAHEAD BY WELMATE LIDOCAINE 5% ROLL-ON- lidocaine 5% solution
OTC PHARM LLC

WelAhead by Welmate Lidocaine 5% Roll-on 83833-101

Active Ingredient

Lidocaine HCl 5%

Purporse

Topical Analgesic

Use

Temporarily Relieves minor pain

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than week without consulting a doctor

When using this product:

- use cnly as directed. Read and follow all directions and warnings on this carton
- do not allow contact with the eyes and mucous membranes
- do not bandage or apply a local heat (such as heating pads) to the area of use

Stop use and aska doctor if

- condition worsens
- skin reactions occur, such as rash, itching, redness, irritation, pain, and swelling
- symptoms persist for more than 7 days or clear up and occur again within a days

Flammable

- keep away from fire or flame

If pregnant or breast freding, 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.

Directions

Adults and children over 12 years:

apply a thin layer to affeced area every 6 to 8 hours, not to exceed 3 applications in a 24 hour period

Children 12 years and younger: ask a doctor

Inactive Ingrediants

purified water, ethyl alcohol, propylene glycol, polysorbate 20, triethanolamine, phenoxyethanol, ethylhexylglycerin,

potassium carbomer, aloe vera, glycerin, chonüoitin sulfate, glucosamine sulfate, methylsulfonylmethane

WELAHEAD BY WELMATE LIDOCAINE 5% ROLL-ON

lidocaine 5% solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83833-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE ANHYDROUS (UNII: EC2CNF7XFP) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM CARBONATE (UNII: BQN1B9B9HA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:83833-101-03	90 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2023	

Labeler - OTC PHARM LLC (119131224)

Registrant - OTC PHARM LLC (119131224)