3CE DRAWING LIP CHILLING- lanolin lips tick Nanda Co., Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

Active Ingredient: Lanolin 2.0%

INACTIVE INGREDIENT

Inactive Ingredients: Mica, Hydrogenated Coco-Glycerides, Red 27 Lake (CI 45410), Red 7 Lake (CI 15850), Rhus Succedanea Fruit Wax, Stearic Acid, Iron Oxides(CI 77499), Triethylhexanoin, Hydrogenated Castor Oil, Acetylated Sucrose Distearate, Microcrystalline Wax, Butylparaben

PURPOSE

Purpose: Lip Protectant

CAUTION

CAUTION: 1. If following problems occur upon using the product, stop use immediately; further use may worsen the symptoms. Consult with a dermatologist if necessary. 1) Red spots, swelling, itchiness, irritation, or any other irregularities. 2) If applied area shows above symptoms when exposed to direct sunlight. 2. Do not use on areas with skin conditions such as open wound, eczema, or any skin disease. 3. Notes on storage and handling 1) Always put the lid back on after use 2) Keep away from reach of children 3) Keep away from high/low temperature or direct sunlight

KEEP OUT OF REACH OF CHILDREN

Keep away from reach of children

INSTRUCTIONS

INSTRUCTIONS: Pencil-type lipstick that glides on lips like a crayon.

Directions

Directions: Hold the pencil flat against the lip and apply by tracing your natural lip line, moving towards to fill in.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



3CE DRAWING LIP CHILLING

lanolin lipstick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-111	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Lanolin (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	Lanolin	0.02 g in 1.1 g	

Inactive Ingredients				
Ingredient Name	Strength			
Mica (UNII: V8A1AW0880)				
Stearic Acid (UNII: 4ELV7Z65AP)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:60764-111-02	1 in 1 CARTON	08/01/2016	
1 NDC:60764-111-01	1.1 g in 1 BOTTLE; Type 0: Not a Combination Product		

l	Marketing Infor	rmation		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

5 5 7	* *	· .		9
unapproved drug other			08/01/2016	

Labeler - Nanda Co., Ltd (557816075)

Registrant - Nanda Co., Ltd (557816075)

Establishment				
Name	Address	ID/FEI	Business Operations	
Nanda Co., Ltd		557816075	manufacture(60764-111)	

Revised: 10/2016 Nanda Co., Ltd