## ETHEREAL SKIN CALMING MOISTURIZING CREAM- dimethicone cream Donegal Bay Ltd

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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### **Daily Moisturizing Lotion**

Active Ingredient:

Dimethicone 2.0%

Purpose:

Skin Protectant

Uses:

Relieves and helps prevent dry, itchy skin. Specially formulated to moisturize, calm, and soothe your skin.

Warnings:

For external use only

When using this product, avoid contacting with eyes

In case of accidental ingestion get medical help or contact a Poison Control Center immediately.

Keep out of reach of children.

Direction:

Smooth over irritated, dry skin daily or as needed. For best results apply immediately after shower or/and bath.

**Inactive Ingredients:** 

Water, Glycerin, Cetyl Palmitate, Mineral Oil, Colloidal Oatmeal, Caprylic/Capric Triglyceride, Octyldodecanol, Cetyl Alcohol, Glyceryl Stearate, PEG-40 Stearate, Carbomer, Sodium Hydroxide, Phenoxyethanol, Benzyl Alcohol, Methylparaben, Propylparaben, DMDM Hydantoin

# **Ethereal**

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## Ethereal<sup>™</sup>SKIN CALMING

Ethereal,", non-greasy, gentle formulation combines rich moisturizers and natural oatmeal to comfort and soothe dry itchy skin.

MOISTURIZING CREME

- Provides 24 hour additional moisture
- Fragrance Free
- Soothes Dry, itchy skin
- Emollient rich, natural oatmeal formula

#### **Drug Facts**

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\*This product is not manufactured or distributed by Beiersdorf Inc





donegal bay Cleveland, OH 44128

www.donegalbayusa.com





with Natural Oatmeal &

Prevents & Soothes dry, ithcy skin

Rich Moisturizers

#### **Fragrance Free**

Skin

CREME

**Calming** 

MOISTURIZING

Lightweight Moisturizer yet Rich

Compare to Eucerin®

net wt. 8.5 oz. / 252 mL

ETHEREAL CREME UPC# 0-47977-99084-2 Style # 99084 dimethicone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70990-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CETYL PALMITATE (UNII: 5ZA2S6B08X)			
MINERAL OIL (UNII: T5L8T28FGP)			
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)			
OCTYLDODECANOL (UNII: 461N1O614Y)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
PEG-40 STEARATE (UNII: ECU18C66Q7)			
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
DMDM HYDANTO IN (UNII: BYR0546 TOW)			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:70990-003-01	252 mL in 1 TUBE; Type 0: Not a Combination Product	10/19/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	10/19/2016		

## Labeler - Donegal Bay Ltd (068443618)

### Registrant - Donegal Bay Ltd (068443618)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
HANGZHOU KARIC COMMODITIES CO., LTD		526884335	manufacture(70990-003)	

Revised: 10/2016 Donegal Bay Ltd