

**NOVANA MOISTURIZING - dimethicone cream**  
**NOVANA MEDICAL 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.*

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**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Dimethicone 2%.....	Skin Protectant

**Uses** Helps to prevent and temporarily protect chafed, chapped, or cracked skin.

**Warnings**

**When using this product** • Do not get into eyes. **Stop use and ask doctor if:** • Condition worsens • Symptoms last more than 7 days or clear up and occur again within a few days. **Do not use on:** Deep or puncture wounds • Animal bites • Serious burns.

**For external use only.**

**Inactive ingredients**

Water, Lanolin Oil, Cod Liver Oil, Propylene Glycol, Polyethylene, Sodium Polyacrylate, Cetyl Alcohol, Beeswax, Glyceryl Stearate, Caprylic/Capric Triglyceride, Sodium Acrylate/Sodium AcryloyldimethylTaurate Copolymer, Sodium Laureth Sulfate, Diazolidinyl Urea, Methylparaben, Propylparaben, Fragrance.

**Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Apply as needed.

NDC 76077-200-09



# Moisturizing Skin Protectant Cream

Once A Day Cream  
Nourishes, conditions and protects dry or irritated skin



Net Wt 9 oz. (255g) e

Patient's Name:

Room:

### Drug Facts

Active Ingredient	Purpose
Dimethicone 8%	Skin Protectant

**Uses** Helps prevent and temporarily protect chafed, chapped, or cracked skin.

**Warnings**  
For external use only.

**When using this product** • Do not get into eyes. **Stop use and ask doctor if** • Condition worsens • symptoms last more than 7 days or clear up and occur again within a few days **Do not use on** • deep or puncture wounds • animal bites • serious burns

**Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
Apply as needed.

**Other information?** • Store at room temperature 15°-30°C (59°-85°F).

**Inactive ingredients**  
Water, Lanolin Oil, Cod Liver Oil, Propylene Glycol, Polyethylene, Sodium Laureth Sulfate, Sodium Polyacrylate, Cetyl Alcohol, Yellow Beeswax, Glyceryl Stearate, Caprylic/Capric Triglyceride, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Diszolidinyl Urea, Methylparaben, Propylparaben, Fragrance.

**Questions or Comments? Call: 1-855-229-2031**

Distributed by: Novana Medical, LLC  
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1-855-229-2031 www.novana-medical.com  
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## NOVANA MOISTURIZING

dimethicone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76077-200
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	.02 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Lanolin</b> (UNII: 7EV65EAW6H)	
<b>Cod Liver Oil</b> (UNII: BBL281NWFG)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>SODIUM POLYACRYLATE (250000 MW)</b> (UNII: 05115JN12J)	

<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (4000000 MW)</b> (UNII: 1DXE3F3OZX)	
<b>Sodium Laureth Sulfate</b> (UNII: BPV390UAP0)	
<b>Diazolidinyl Urea</b> (UNII: H5RIZ3MPW4)	
<b>Methylparaben</b> (UNII: A28C7H9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76077-200-04	120 mL in 1 TUBE		
2	NDC:76077-200-07	210 mL in 1 TUBE		
3	NDC:76077-200-09	270 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/04/2012	

**Labeler** - NOVANA MEDICAL LLC (964916600)

**Registrant** - O.L. PRODUCTS, INC. (961405883)

### Establishment

Name	Address	ID/FEI	Business Operations
O.L. PRODUCTS, INC.		961405883	label, manufacture

Revised: 4/2012

NOVANA MEDICAL LLC