

**NOVANA PROTECT BARRIER - zinc oxide 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>
Zinc Oxide 12%.....	Skin Protectant

**Warnings**

**For external use only.**

**When using this product** • Do not get in 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

**Inactive ingredients**

Cetyl Alcohol, Cod Liver Oil, Diazolidinyl Urea, Dimethicone, Glyceryl Stearate, Lanolin Oil, Methylparaben, Petrolatum, Propanediol, Propylene Glycol, Propylparaben, Sodium Laureth Sulfate, Water



NDC 76077-300-07



# Skin Protectant Cream

**Moisture Barrier Cream**  
Provides a protective barrier to help seal out wetness

Net Wt 7 oz. (198g)e

Patient's Name: \_\_\_\_\_  
Room: \_\_\_\_\_

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Zinc Oxide 12%.....	Skin Protectant
<b>Uses</b> Helps treat and prevent minor skin irritation.	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>When using this product:</b> • Do not get in eyes. • <b>Stop use and ask doctor</b> if condition worsens • symptoms last more than 7 days or clear up and occur again within a few days	
<b>Do not use on:</b> • deep or puncture wounds • animal bites • serious burns	
<b>Keep this and all drugs out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Apply as needed	
<b>Other Information?</b> • Store at room temperature 15°-30°C (59°-86°F).	
<b>Inactive ingredients</b>	
Cetyl Alcohol, Cod Liver Oil, Diazolidinyl Urea, Dimethicone, Glyceryl Stearate, Lanolin Oil, Methylparaben, Petrolatum, Propanediol, Propylene Glycol, Propylparaben, Sodium Laureth Sulfate, Water	
Questions or Comments? Call: 1-855-229-2031	

Distributed by: Novana Medical, LLC  
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1-855-229-2031 www.novanamedical.com  
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## NOVANA PROTECT BARRIER

zinc oxide cream

<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76077-300
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	.12 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Lanolin</b> (UNII: 7EV65EAW6H)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Cod Liver Oil</b> (UNII: BBL281NWFQ)	
<b>Petrolatum</b> (UNII: 4T6H12BN9U)	
<b>Propanediol</b> (UNII: 5965N8W85T)	
<b>Sodium Laureth Sulfate</b> (UNII: BPV390UAP0)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Diazolidinyl Urea</b> (UNII: H5RIZ3MPW4)	
<b>Methylparaben</b> (UNII: A218C7H9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76077-300-04	120 mL in 1 TUBE		
2	NDC:76077-300-07	210 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	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