

**NOVANA ALL-IN-ONE ONE STEP PERINEAL - dimethicone lotion**  
**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.*

**Drug Facts**

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

**Uses** Temporarily protects and helps relieve chapped or cracked skin.

**Warnings**

**For external use only.**

**When using this product** • Avoid contact with eyes • **Stop use and ask doctor if** • 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.

**For external use only.**

**Directions** • Apply as needed. • Change wet and soiled undergarments. • Apply to affected area and gently wipe with clean, soft cloth. • Use with each undergarment change, especially at bedtime or any time when exposure to wet garments may be prolonged.

**Inactive ingredients**

Water, Cetyl Alcohol, Stearyl Alcohol, Glycine Soja (Soybean) Oil, Propanediol, Polysorbate 60, Panthenol, Glycerin, Isopropyl Myristate, Allantoin, Tocopherol, Sodium Laureth Sulfate, Citric Acid, Phenoxyethanol, Iodopropynyl Butylcarbamate

<b>NOVANA ALL-IN-ONE ONE STEP PERINEAL</b>			
dimethicone lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:760 77-500
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
Soybean Oil (UNII: 241ATL177A)	
Propanediol (UNII: 5965N8W85T)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Panthenol (UNII: WV9CM0O67Z)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Allantoin (UNII: 344S277G0Z)	
Tocopherol (UNII: R0ZB2556P8)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76077-500-08	240 mL in 1 BOTTLE, SPRAY		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	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