DERMA CIDOL 2000- chloroxylenol liquid
Rosedale Therapeutics, 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.

Derma CIDOL 2000

Active Ingredient:

0.5% Chloroxylenol

Purpose

Healthcare Personnel Handwash

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Use decreases the level of transient microorganisms on the skin before contact with patients under medical care or treatment.

Warning **For external use only**

Stop use and ask a doctor if irritation and redness develop and persist for more than 5 days.

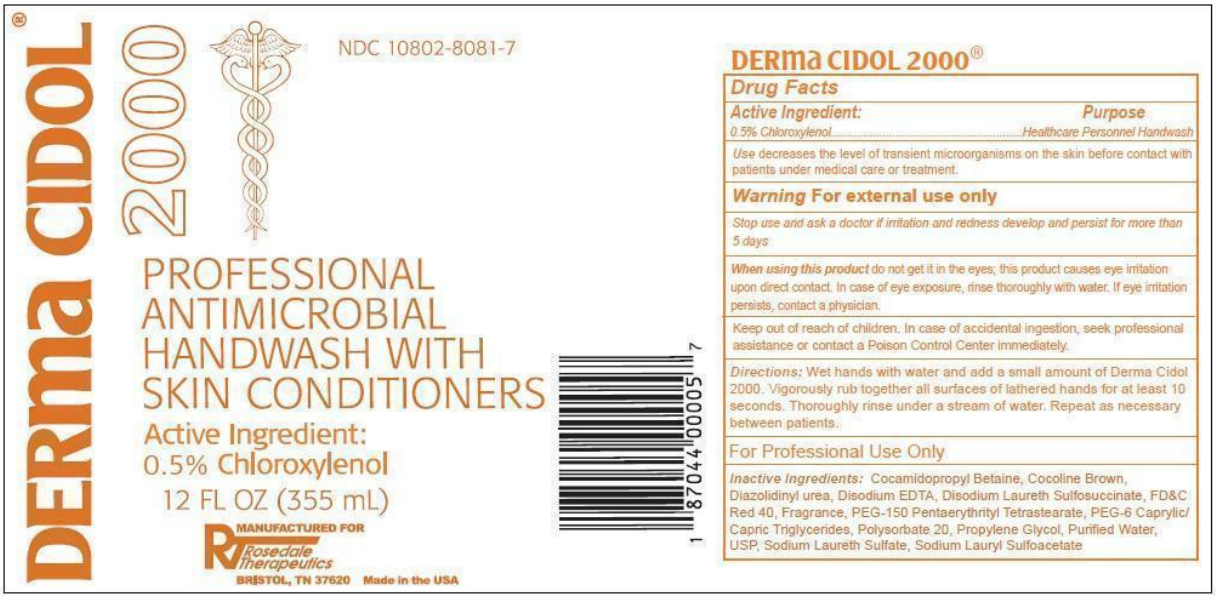
When using this product do not get it in the eyes; this product causes eye irritation upon direct contact. In case of eye exposure, rinse thoroughly with water. If eye irritation persists, contact a physician.

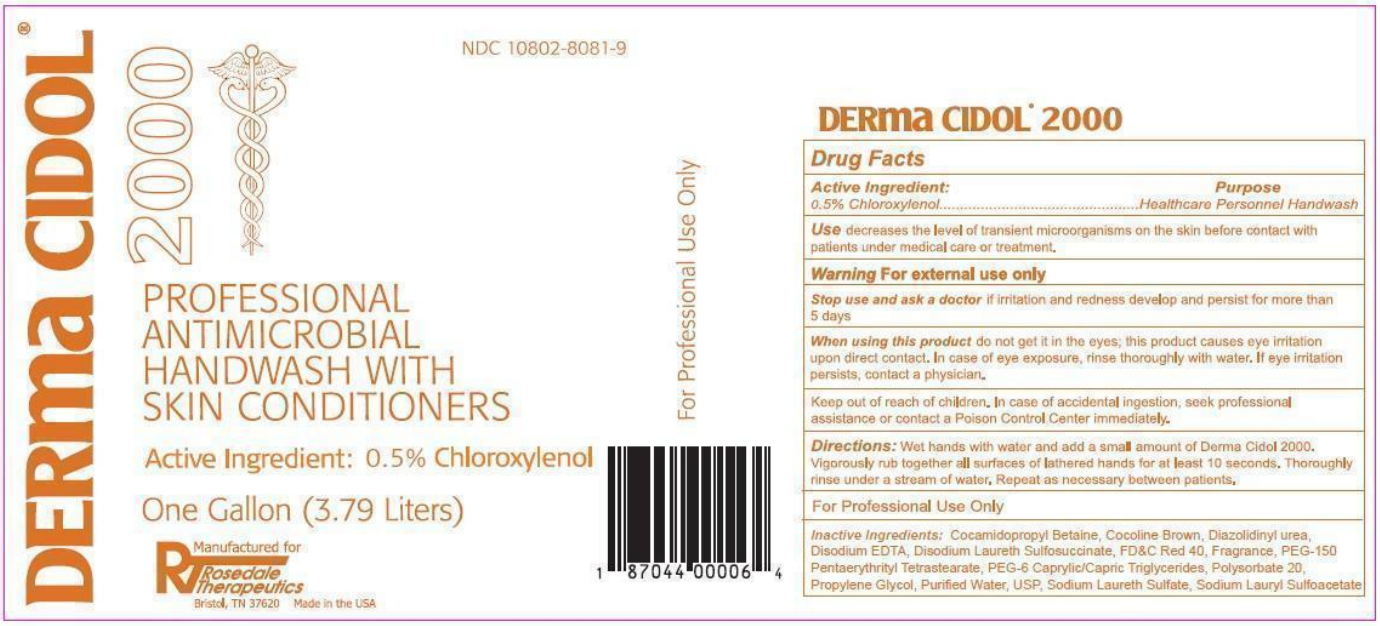
Directions: Wet hands with water and add a small amount of Derma Cidol 2000. Vigorously rub together all surfaces of lathered hands for at least 10 seconds. Thoroughly rinse under a stream of water. Repeat as necessary between patients.

For Professional Use Only

Inactive Ingredients: Cocamidopropyl Betaine, Cocoline Brown, Diazolidinyl urea, Disodium EDTA, Disodium Laureth Sulfosuccinate, FD&C Red 40, Fragrance, PEG-150, Pentaerythrityl Tetrastearate, PEG-6 Caprylic/Capric Triglycerides, Polysorbate 20, Propylene Glycol, Purified Water USP, Sodium Laureth Sulfate, Sodium Lauryl Sulfoacetate

Packaging





DERMA CIDOL 2000

chloroxylenol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10802-8081
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 7000 (UNII: Q0JET65GEL)	
PENTAERYTHRITYL TETRASTEARATE (UNII: W9Q3DZS0EG)	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10802-8081-7	355 mL in 1 CONTAINER		
2	NDC:10802-8081-9	3790 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/18/2015	

Labeler - Rosedale Therapeutics, LLC (161264622)

Establishment

Name	Address	ID/FEI	Business Operations
Ei LLC		105803274	manufacture(10802-8081)

Revised: 2/2015 Rosedale Therapeutics, LLC