

HYDROLATUM- white petrolatum cream
Denison Pharmaceuticals, LLC

Hydrolatum

White Petrolatum, 54%

Skin Protectant

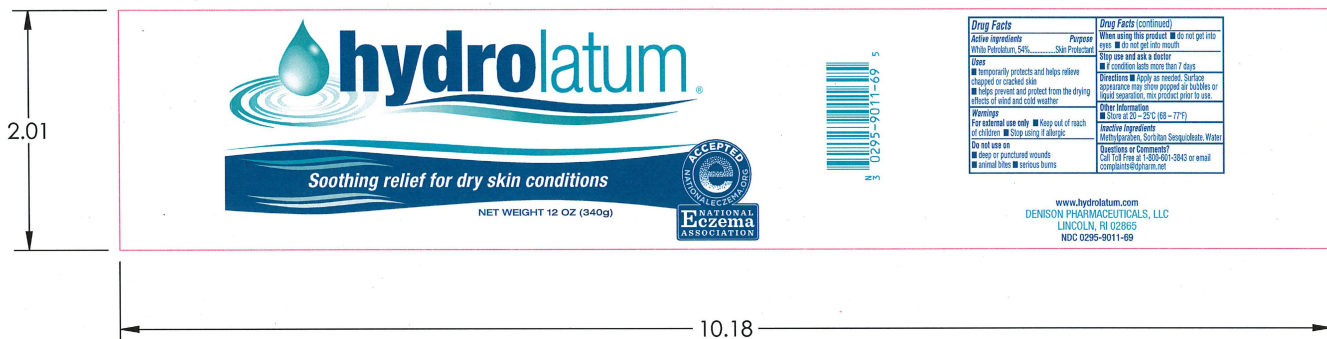
- temporarily protects and helps relieve chapped or cracked skin
- helps prevent and protect from the drying effects of wind and cold weather
- for external use only
- Keep out of reach of children
- Stop using if allergic
- do not get into eyes
- do not get into mouth
- if condition lasts more than 7 days
- apply as needed
- Store at 20-25C (68-77F)

Methylparaben, Purified Water, Sorbitan Sesquioleate

Call Toll Free at 1-800-601-3843 or email complaints@dpharm.net

- deep or punctured wounds
- animal bites
- serious burns

Keep out of reach of children



HYDROLATUM			
white petrolatum cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-9011

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	45 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)			
	METHYLPARABEN (UNII: A2I8C7HI9T)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9011-13	57 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2020	
2	NDC:0295-9011-36	454 g in 1 JAR; Type 0: Not a Combination Product	02/19/2020	
3	NDC:0295-9011-69	340 g in 1 JAR; Type 0: Not a Combination Product	09/12/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M016	02/19/2020		

Labeler - Denison Pharmaceuticals, LLC (001207208)

Establishment			
Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(0295-9011)

Revised: 10/2023

Denison Pharmaceuticals, LLC