

**HERBITUAL SKIN PROTECTANT CREAM- dimethicone cream**  
**Prime Matter Labs West**

*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.*

-----  
**Herbital ATOPIC SKINN DEFENSE Skin Protectant Cream**

***Active Ingredient***

Dimethicone 1%

***Purpose***

Skin Protectant

***Uses***

Helps prevent and temporarily protects and helps relieve, chapped or cracked skin.

***Warnings***

**For external use only**

**When using this product:**

do not get into eyes.

**Stop use and ask a 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 out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**

Apply as needed. For best results, apply to damp skin after bathing or showering.

***Inactive Ingredients:***

Water, Emu Oil, Caprylic/Capric Triglyceride, Butyrospermum Parkii Butter, Glycerin, Glyceryl Stearate SE, Stearyl Alcohol, Euphorbia Cerifera Wax, Curcuma Longa Root Extract, Aconitum Carmichaelli Root Extract, Astragalus Membranaceous Root Extract, Coptis Chinensis Root Extract, Glycyrrhiza Uralensis Root Extract, Phellodendron Chinese Bark Extract, Rheum Plamatum Root Extract, Salvia Miltiorrhiza Root Extract, Sophora Flavescens Root Extract, Phenoxyethanol, Xanthan Gum, Caprylyl Glycol, Potassium Sorbate, Sodium Benzoate, Ethylhexylglycerin, Hexylene Glycol.

**Distributed by Herbitual LLC.**

2699 1/2 N Beachwood Drive

Suite 212 Los angeles CA 90068

www.herbitualskin.com | @herbitualskin

**Herbitual  
ATOPIC SKINN DEFENSE  
Skin Protectant Cream**



**HERBITUAL SKIN PROTECTANT CREAM**

dimethicone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82956-0001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE 100</b> (UNII: RO266O364U) (DIMETHICONE 100 - UNII:RO266O364U)	DIMETHICONE 100	9.98 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>TURMERIC</b> (UNII: 856YO1Z64F)	
<b>ACONITUM CARMICHAELII ROOT</b> (UNII: XJ28061U1S)	
<b>RHEUM PALMATUM ROOT</b> (UNII: G025DAL7CE)	
<b>SALVIA MILTIORRHIZA ROOT</b> (UNII: 1693AM5SBN)	
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>ASTRAGALUS MONGHOLICUS ROOT</b> (UNII: 922OP8YUPF)	
<b>PHELLODENDRON AMURENSE BARK</b> (UNII: PBG27B754G)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EMU OIL</b> (UNII: 344821WD61)	
<b>GLICYRRHIZA URALENSIS ROOT</b> (UNII: 42B5YD8F0K)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>COPTIS CHINENSIS ROOT</b> (UNII: CXS4LJR7EL)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82956-0001-3	28 mL in 1 JAR; Type 0: Not a Combination Product	01/24/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/24/2023	

**Labeler** - Prime Matter Labs West (118568102)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Matter Labs West		118568102	manufacture(82956-0001) , pack(82956-0001) , label(82956-0001)

Revised: 1/2023

Prime Matter Labs West