MOISTUREWORX- white petrolatum spray Juventio 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.

MoistureWORX™ Skin Protection Spray (30% White Petrolatum, USP)

Drug Facts

Active Ingredient

White Petrolatum, USP 30%

□*Purpose*

Skin Protectant Spray

$\square Use$

- Temporarily protects chapped or cracked skin
- Helps protect from the drying effects of wind and cold weather

□ Warnings

IFor external use only

When using this product

• Ido not get into eyes

See a doctor if

• Condition lasts more than 7 days.

Do not use on

- Ideep 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

Inactive Ingredients

Water, Glyceryl Distearate, Steareth-10, Cholesterol, Sodium Laureth Sulfate, Polysorbate 80, Propylene Glycol, Methylparaben, Diazolidinyl Urea, Propylparaben

Principal Display Panel - Bottle Label

NDC 58155-131-01

Mois ture WORXTM

Skin Protection Spray

(30% white petrolatum, USP)

Patented nanotechnology formula is clinically proven to gently moisturize and protect the skin

- non-greasy
- hypoallergenic
- won't clog your pores

$\square DERMWORX^{TM}$

PROFESSIONAL SKINCARE

4 fl. oz. (120 mL)

NDC 58155-131-01

Moisture WORX™

Skin Protection Spray (30% white petrolatum, USP)

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DERMWORXTM

4 fl. oz. (120 mL)

Principal Display Panel - Carton Label

NDC 58155-131-01

 $Mositure WORX^{\tiny{TM}}$

Skin Protection Spray

(30% white petrolatum, USP)

Clinically proven nanotechnology formulation moisturizes and protects the skin

The MoistureWorxTM fine mist spray is non-greasy, hypoallergenic and won't clog your pores

 $DERMWORX^{\tiny{TM}}$

PROFESSIONAL SKINCARE

4 fl. oz. (120 mL)

Moisture WORX™

Skin Protection Spray (30% white petrolatum, USP)

Clinically proven nanotechnology formulation moisturizes and protects the skin

The MoistureWorx™ fine mist spray is non-greasy, hypoallergenic and won't clog your pores



4 fl. oz. (120 mL)

MOISTUREWORX

white petrolatum spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58155-131
Route of Administration	TOPICAL		

	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERYL DISTEARATE (UNII: 73071MW2KM)			
STEARETH-10 (UNII: FD0913P475)			
CHOLESTEROL (UNII: 97C5T2UQ7J)			
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)			
PROPYLPARABEN (UNII: Z8 IX2SC1OH)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58155-131-01	1 in 1 CARTON		
1		120 mL in 1 BOTTLE, SPRAY		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/26/2013	

Labeler - Juventio LLC (078752736)

Establishment			
Name	Address	ID/FEI	Business Operations
IGI Laboratories, Inc.		011036910	MANUFACTURE(58 155-131), analysis(58 155-131)

Revised: 8/2014 Juventio LLC