# UNIVERSAL LAVENDER SCENT PETROLEUM- white petroleum jelly Universal Distribution Center 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.

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#### UNIVERSAL LAVENDER SCENT PETROLEUM

### **Active ingredient**

White Petrolatum USP (99.9 %)

# **Purpose**

Skin Protectant

#### Uses

- For the temporary protection of minor cuts, scrapes, burns and sunburn.
- Helps to temporarily protect chafed, chapped, cracked or windburned skin and lips.

# Warnings

# For External Use Only.

**Do not use**over deep or puncture wounds, infections or lacerations. Ask a doctor.

When using this productavoid contact with eyes.

**Stop use and ask doctor**if condition worsens or does not improve within 7 days.

**Keep out of reach of children**if swallowed get medical help or contact a Poison Control Center right away.

#### **Directions**

Apply product as liberally, as often as necessary.

# Inactive ingredients

Fragrance

#### PRINCIPAL DISPLAY PANEL

Universal Lavender Scent Petroleum Jelly Net wt. 13 oz (368 g)



#### **Drug Facts** Drug Facts (continued) **Active Ingredient** Purpose Stop use and ask doctor White Petrolatum USP (99.9%)..... if condition worsens or improve within 7 days. Uses: • For the temporary protection of minor cuts, scrapes, burns and sunburn. • Helps to temporarily protect chafed, chapped, cracked or winburned skin and lips. Keep out of reach of children if swallowed get medical help or contact a Poison Control Center right away. Warnings: For External Use Only Directions: Apply product Do not use over deep or puncture wounds, liberally, as often as necessary. When using this product avoid contact Inactive Ingredient: Fragrance Distrubuted By: Universal Distribution Center L.L.C. Edison, NJ-08817 86023

NET WT. 13oz (368g)

# UNIVERSAL LAVENDER SCENT PETROLEUM

white petroleum jelly

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52000-150

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)

PETROLATUM 99.9 g in 100 g

#### **Inactive Ingredients**

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:52000-150- 01	170 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019				
2	NDC:52000-150- 02	226 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019				
3	NDC:52000-150- 03	368 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019				
4	NDC:52000-150- 04	510 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019				

Marketing Information							
Marketing	Application Number or Monograph	Marketing Start	Marketing End				

Category	Citation	Date	Date
OTC monograph final	part347	11/01/2019	

# **Labeler -** Universal Distribution Center LLC (019180459)

# **Registrant -** Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Jell Pharmaceuticals Pvt Ltd		726025211	manufacture(52000-150)				

Revised: 9/2023 Universal Distribution Center LLC