# UNIVERSAL BABY FRESH 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 BABY FRESH 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 product avoid 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 Baby fresh Scent Petroleum Jelly Net Wt. 13 OZ (368 g)





# UNIVERSAL BABY FRESH SCENT PETROLEUM

white petroleum jelly

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52000-118

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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:52000-118- 01	170 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
2	NDC:52000-118- 02	226 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
3	NDC:52000-118- 03	368 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
4	NDC:52000-118- 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	Business Operations
Jell Pharmaceuticals Pvt Ltd		726025211	manufacture(52000-118)

Revised: 11/2022 Universal Distribution Center LLC