

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.

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

None

PRINCIPAL DISPLAY PANEL

UNIVERSAL BABY FRESH SCENT PETROLEUM
SKIN PROTECTANT
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:52000-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.99 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-006-19	226 g in 1 JAR		
2	NDC:52000-006-20	45 g in 1 JAR		
3	NDC:52000-006-21	100 g in 1 JAR		
4	NDC:52000-006-22	113 g in 1 JAR		
5	NDC:52000-006-23	170 g in 1 JAR		
6	NDC:52000-006-24	198 g in 1 JAR		
7	NDC:52000-006-25	283 g in 1 JAR		
8	NDC:52000-006-26	368 g in 1 JAR		
9	NDC:52000-006-27	450 g in 1 JAR		
10	NDC:52000-006-28	500 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	02/06/2013	

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(52000-006)

Revised: 2/2013

Universal Distribution Center LLC