BABY FRESH SCENT PETROLEUM- white petroleum jelly Jell Pharmaceuticals Pvt Ltd.

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

Fragrance

PRINCIPAL DISPLAY PANEL

Universal Baby fresh Scent Petroleum Jelly Net Wt. 13 OZ (368 g)



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BABY FRESH SCENT PETROLEUM

white petroleum jelly

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30400-703	
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:30400-703- 01	170 g in 1 JAR; Type 0: Not a Combination Product	02/15/2022	
2	NDC:30400-703- 02	226 g in 1 JAR; Type 0: Not a Combination Product	02/15/2022	
3	NDC:30400-703- 03	368 g in 1 JAR; Type 0: Not a Combination Product	02/15/2022	
4	NDC:30400-703- 04	510 g in 1 JAR; Type 0: Not a Combination Product	02/15/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/15/2022	

Labeler - Jell Pharmaceuticals Pvt Ltd. (726025211)

Registrant - Jell Pharmaceuticals Pvt Ltd. (726025211)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(30400-703)	

Revised: 2/2022 Jell Pharmaceuticals Pvt Ltd.