

PETROLEUM- white petroleum jelly
Blue Cross Laboratories, Inc.

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 (100 %)

Purpose

Skin protectant

Uses

- helps to soothe dry, chapped, cracked or irritated skin and lip due to cold and wind
- for the temporary protection of minor cuts, scrapes, burns and sunburn

Warnings

For external use only

Avoid contact with eyes

Stop use and ask a doctor if condition worsens or does not improve after 7 days.

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

Directions

- apply liberally, as often as necessary

Inactive ingredients

None

PRINCIPAL DISPLAY PANEL

PETROLEUM JELLY

Skin Protectant

NET WT. 6 OZ (170 g)



Drug Facts	
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Directions ■ apply liberally, as often as necessary	

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Manufactured for
BLUE CROSS LABORATORIES
Santa Clarita, CA 91350
Made in India

PETROLEUM

white petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:22431-705
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22431-705-01	113 g in 1 JAR; Type 0: Not a Combination Product	02/25/2019	
2	NDC:22431-705-02	170 g in 1 JAR; Type 0: Not a Combination Product	02/25/2019	
3	NDC:22431-705-03	226 g in 1 JAR; Type 0: Not a Combination Product	02/25/2019	
4	NDC:22431-705-04	270 g in 1 JAR; Type 0: Not a Combination Product	02/25/2019	
5	NDC:22431-705-05	368 g in 1 JAR; Type 0: Not a Combination Product	02/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/25/2019	

Labeler - Blue Cross Laboratories, Inc. (008298879)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(22431-705)

Revised: 3/2019

Blue Cross Laboratories, Inc.