PURE PETROLATUM JELLY- petrolatum 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.

Petroleum Jelly

Active Ingredient

White Petrolatum (100% w/w)

Purpose

Skin protectant

Uses

- temporarily protects minor cuts, scrapes, burns and sunburn
- temporarily protects and helps relieve chapped or cracked skin
- helps protect from the drying effects of wind and cold weather
- helps treat and prevent diaper rash
- helps seal out wetness

Warnings:

For external use only

When using this product

• do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clean up and occur again in a few days

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

• If swallowed, get medical help or contact a Poison Control Center right away

Directions

· apply as needed

Inactive Ingredient

none

Package Label







PURE PETROLATUM JELLY

petrolatum jelly

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30400-509	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	100 g in 100 g	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	100 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:30400-509- 01	368 g in 1 JAR; Type 0: Not a Combination Product	10/15/2016	
	2	NDC:30400-509- 02	226 g in 1 JAR; Type 0: Not a Combination Product	10/15/2016	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/15/2016	

Labeler - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment					
Name	Address	ID/FEI	Business Operations		
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(30400-509)		

Revised: 10/2021 Jell Pharmaceuticals Pvt. Ltd.