SHEA BUTTER PETROLEUM JELLY- petrolatum jelly 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 (99.6%)

Purpose

Skin Protectant

Uses

temporarily protects minor: cuts, scrapes, burns; temporarily protects and helps relieve chapped or cracked skin and lips; helps protect from the drying effects of wind and cold weather

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 longer than 7 days or clear up and occur again within 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

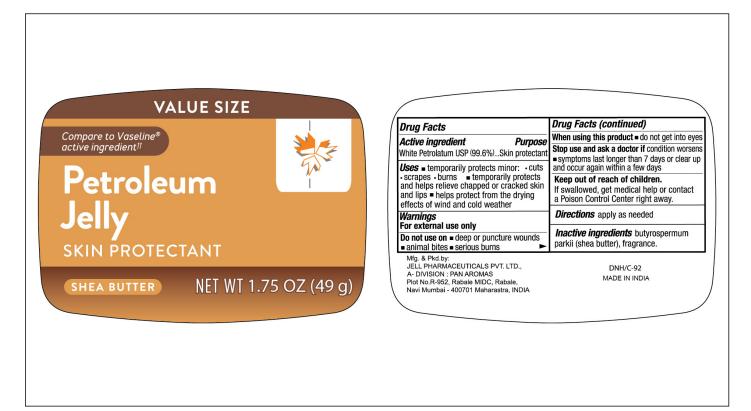
Inactive ingredients

butyrospermum parkii (shea butter), fragrance

Questions or comments?

1-800-925-4733

Label



SHEA BUTTER PETROLEUM JELLY

petrolatum jelly jelly

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30400-501	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.6 g in 100 g		

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	0.1 g in 100 g

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30400-501- 01	368 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
2	NDC:30400-501- 02	49 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
3	NDC:30400-501- 03	100 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
4	NDC:30400-501- 04	113 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
5	NDC:30400-501- 05	170 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
6	NDC:30400-501- 06	425 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
7	NDC:30400-501- 07	226 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		
8	NDC:30400-501- 08	283 g in 1 JAR; Type 0: Not a Combination Product	10/11/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	05/10/2021		

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(30400-501)		