

PRINCESS PETROLEUM- white petrolatum jelly
Ultra Distributors 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.

Princess Petroleum Jelly

Active Ingredient

White petrolatum USP (100%)

Purpose

Skin protectant

Uses

helps protect chapped skin

Warnings

For external use only

When using this product

- do not get into eyes

See a doctor if condition lasts more than 7 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

None

PRINCIPAL DISPLAY PANEL

PRINCESS PETROLEUM JELLY

NET WT 6 OZ (170 gm)



PRINCESS PETROLEUM

white petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78495-004
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78495-004-01	113 g in 1 JAR; Type 0: Not a Combination Product	12/01/2020	
2	NDC:78495-004-02	170 g in 1 JAR; Type 0: Not a Combination Product	12/01/2020	
3	NDC:78495-004-03	226 g in 1 JAR; Type 0: Not a Combination Product	12/01/2020	
4	NDC:78495-004-04	368 g in 1 JAR; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/01/2020	

Labeler - Ultra Distributors Inc. (007160073)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(78495-004)

Revised: 12/2020

Ultra Distributors Inc.