

BUDPAK PETROLEUM- petroleum jelly
Budpak 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.

BUDPAK PETROLEUM JELLY

Active Ingredient

White Petrolatum USP (100%)

Purpose

Skin Protectant

Uses

- Temporarily protects minor cuts, scrapes or 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

- conditions last 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

BUDPAK PETROLEUM JELLY

NET WT. 8 OZ. (226g)



Drug Facts	
Active Ingredient.....	Purpose
White Petrolatum USP (100%)	Skin Protectant
<p>■ 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. See a doctor if conditions last 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 Poison Control Center right away. ■ Directions: Apply as needed.</p> <p>*This product is not manufactured or distributed by Unilever, owner of the registered trademark Vaseline®.</p>	
DNHC-92  6 10499 00019 3	<p>Manufactured in India. Distributed by Budpak, Inc. 100 North Drive Ronkonkoma, NY 11779 ©2014 Budpak, Inc.</p>

BUDPAK PETROLEUM

petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-033
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:27293-033-06	113 g in 1 BOTTLE		
2	NDC:27293-033-13	170 g in 1 BOTTLE		
3	NDC:27293-033-12	226 g in 1 BOTTLE		
4	NDC:27293-033-07	283 g in 1 BOTTLE		
5	NDC:27293-033-11	368 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/07/2014	

Labeler - Budpak Inc. (183224849)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(27293-033)

Revised: 7/2014

Budpak Inc.