

HEALTH SMART BABY PETROLEUM- white petroleum jelly

Home Smart Products

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 Petroleum (99.9%)

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.

Warning:

For External Use Only.

Do not use on:

- deep or puncture wounds
- lacerations or infections
- serious burns
- animal bites

Stop use and ask doctor

- if condition does not improve or lasts more than 7 days.

Keep out of reach of children

- if swallowed get medical help or contact Poison Control Center right away.
- if redness or swelling develops, consult a physician promptly.

Directions:

Apply as often as necessary.

Inactive Ingredients:

None.

PRINCIPAL DISPLAY PANEL

HEALTH SMART BABY PETROLEUM JELLY

NET WT. 8OZ. (226G)



HEALTH SMART BABY PETROLEUM

white petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	0.1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-015-19	50 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
2	NDC:52862-015-20	100 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
3	NDC:52862-015-14	113 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
4	NDC:52862-015-21	170 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
5	NDC:52862-015-01	226 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
6	NDC:52862-015-22	283 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
7	NDC:52862-015-23	368 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
8	NDC:52862-015-24	425 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
9	NDC:52862-015-25	450 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	
10	NDC:52862-015-26	500 g in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/28/2013	

Labeler - Home Smart Products (161872676)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-015)

Revised: 8/2020

Home Smart Products