# **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.

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## **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 developes, consult a physician promptly.

#### **Directions:**

Apply as often as necessary.

#### **Inactive Ingredients:**

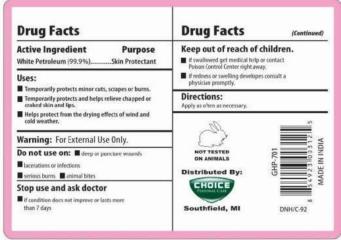
None.

#### 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 NameBasis of StrengthStrengthPETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)PETROLATUM99.9 g in 100 g

## **Inactive Ingredients**

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

0.1 g in 100 g

Packaging								
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>				
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