# PETROLEUM - petrolatum jelly Personal Care Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if the comply with applicable regulations and policies. FDA has not evaluated whether this product complies.
Personal Care
Active ingredients
White Petroleum 99.9%
Purpose skin protectant
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Use
helps prevent diaper rash
Warnings
For external use only
When using this product do not get into eyes
See a doctor if condition worsens or lasts more than 7 days. Do not use on deep puncture wounds, animal bites, serious burns.
Directions
change and cleanse diaper area, and allow to dry
apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged.

Inactive ingredients fragrance





Personal Care
100% Pure Petroleum Jelly
Baby fresh scent
net wt. 3.52 oz (100 g)

Distributed by: Personal Care products, LLC

Troy, Michigan 48084 Made in India

#### **PETROLEUM**

petrolatum jelly

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-8040	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Petrolatum (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	Pe tro la tum	99.9 g in 100 g

### **Inactive Ingredients**

Ingredient Name	Strength

water (UNII: 059QF0KO0R)

#### **Packaging**

#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-8040-2	100 g in 1 CONTAINER		

## **Marketing Information**

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	07/01/2012		

## Labeler - Personal Care Products (966155082)

## Registrant - Personal Care Products (966155082)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jell Pharmaceuticals		726025211	manufacture(29500-8040)	

Revised: 6/2012 Personal Care Products