

**PETROLEUM JELLY- white petrolatum cream**  
**Rejoice International 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.*

-----  
**Petroleum Jelly**

<b>Active Ingredients</b>	<b>Purpose</b>
---------------------------	----------------

White Petroleum 99.9% .....	skin protectant
-----------------------------	-----------------

**Uses**

temporarily protects and helps relieve chapped or cracked skin and lips

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

XtraCare

100% Pure Petroleum Jelly

Baby Fresh Scent

**Directions** apply as needed

- 

**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 puncture wounds
- animal bites
- serious burns

**Inactive ingredients** fragrance

**XtraCare®**

100% Pure

# Petroleum Jelly

**Original Skin Protectant**

NET WT 4 OZ (113 g)

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b> skin protectant	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
<b>Uses</b> temporarily protects and helps relieve chapped or cracked skin and lips		<b>Directions</b> apply as needed
<b>Warnings</b> For external use only When using this product do not get into eyes See a doctor if condition lasts more than 7 days		<b>DISTRIBUTED BY:</b> <b>REJOICE INTERNATIONAL, INC</b> <b>NORTHVILLE, MI 48168 U.S.A.</b> <b>MADE IN INDIA</b>
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
QUESTIONS/COMMENTS? 1-855-345-5575		 8 49607 09200 7

**XtraCare®**

100% Pure

# Petroleum Jelly

**Original Skin Protectant**

NET WT. 6 OZ (170 g)

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b> skin protectant	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
<b>Uses</b> temporarily protects and helps relieve chapped or cracked skin and lips		<b>Directions</b> apply as needed
<b>Warnings</b> For external use only When using this product do not get into eyes See a doctor if condition lasts more than 7 days		<b>DISTRIBUTED BY:</b> <b>REJOICE INTERNATIONAL, INC</b> <b>NORTHVILLE, MI 48168 U.S.A.</b> <b>MADE IN INDIA</b>
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
QUESTIONS/COMMENTS? 1-855-345-5575		 8 49607 09203 8

**XtraCare®**

100% Pure

# Petroleum Jelly

**Original Skin Protectant**

NET WT. 8 OZ (227 g)

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b> skin protectant	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away
<b>Uses</b> temporarily protects and helps relieve chapped or cracked skin and lips		<b>Directions</b> apply as needed
<b>Warnings</b> For external use only When using this product do not get into eyes See a doctor if condition lasts more than 7 days		<b>DISTRIBUTED BY:</b> <b>REJOICE INTERNATIONAL, INC</b> <b>NORTHVILLE, MI 48168 U.S.A.</b> <b>MADE IN INDIA</b>
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
QUESTIONS/COMMENTS? 1-855-345-5575		 8 49607 09206 9



## PETROLEUM JELLY

white petrolatum cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57337-077
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-077-01	113 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
2	NDC:57337-077-02	170 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
3	NDC:57337-077-03	227 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
4	NDC:57337-077-04	368 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/15/2015	

**Labeler** - Rejoice International Inc. (078741245)

**Registrant** - Jell Pharmaceuticals Pvt Ltd. (726025211)

**Establishment**

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(57337-077)

Revised: 11/2022

Rejoice International Inc.