

**BABY 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.*

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**Baby Petroleum Jelly**

<b>Active Ingredients</b>	<b>Purpose</b>
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White Petroleum 99.9% .....	skin protectant
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**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**

- 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

**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



# petroleum jelly

100% Pure

Baby Fresh scent

NET WT 4 OZ (113 g)

### Drug Facts

**Active ingredients** Purpose  
White Petroleum 99.9%..skin protectant

**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

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

### Drug Facts (continued)

**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.

QUESTIONS/COMMENTS? 1-855-345-5575

DISTRIBUTED BY:  
REJOICE INTERNATIONAL, INC  
NORTHVILLE, MI 48168 U.S.A.  
MADE IN INDIA



8 49607 09201 4



# petroleum jelly

100% Pure

Baby Fresh scent

NET WT 6 OZ (170 g)

### Drug Facts

**Active ingredients** Purpose  
White Petroleum 99.9%..skin protectant

**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

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

### Drug Facts (continued)

**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.

QUESTIONS/COMMENTS? 1-855-345-5575

DISTRIBUTED BY:  
REJOICE INTERNATIONAL, INC  
NORTHVILLE, MI 48168 U.S.A.  
MADE IN INDIA



8 49607 09204 5



# petroleum jelly

100% Pure

Baby Fresh scent

NET WT 8 OZ (227 g)

### Drug Facts

**Active ingredients** Purpose  
White Petroleum 99.9%..skin protectant

**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

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

### Drug Facts (continued)

**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.

QUESTIONS/COMMENTS? 1-855-345-5575

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REJOICE INTERNATIONAL, INC  
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MADE IN INDIA



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## BABY PETROLEUM JELLY

white petrolatum cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57337-076
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99 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:57337-076-01	113 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
2	NDC:57337-076-02	170 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
3	NDC:57337-076-03	227 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
4	NDC:57337-076-04	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	
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**Labeler** - Rejoice International Inc. (078741245)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(57337-076)

Revised: 11/2022

Rejoice International Inc.