

PETROLATUM - petrolatum jelly
Dynarex Corporation

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.

Petrolatum Jelly

Active Ingredient	Purpose
White Petrolatum 100%	Skin Protectant

Uses:

- Helps treat and prevent diaper rash
- Helps seal out wetness
- Temporarily protects minor * cuts * scrapes * burns
- Temporarily helps protect and helps relieve chapped and cracked skin and lips
- Helps prevent and protect from the drying effects of wind and cold weather
- Helps prevent and protect chaffed skin or minor skin irritations associated with diaper rash
- With each diaper change, especially at bed time when exposure to wet diapers may be prolonged.

Warnings:

For external use only.

When using this product:

Do not get in eyes.

Stop use and ask a doctor if:

- Condition worsens
- symptoms last more than 7 days or clear up and occur in a few days.

Do not use on:

- Deep or 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

Directions:

- Change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply as needed

Other information:


- Store at room temperature 15 Deg C - 30 Deg C (59 Deg F - 86 Deg F)

- Avoid excessive heat

Indications and Usage

Skin Protectant

Principal Display Panel:

Drug Facts		Drug Facts (continued)	Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com NDC #67777-400-01 Made in India  6 16784 11451 4
Active Ingredient White Petrolatum USP (100% w/w).....Skin Protectant	Purpose	Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again in a few days.	
Uses: • Helps treat and prevent diaper rash • Helps seal out wetness • Temporarily protects minor • cuts • scrapes • burns • Temporarily helps protect and relieve chapped and cracked skin or lips • Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash • With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.		Do not use on • deep puncture wounds • animal bites • serious burns.	
Warnings: For external use only. When using this product • do not get into eyes.		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
		Directions: • Change wet and soiled diapers promptly. • Cleanse the diaper area and allow to dry. • Apply as needed.	
		Other information: • Store at 59°- 86°F (15°-30°C) • Avoid excessive heat.	

Petrolatum_Jelly.jpg

PETROLATUM			
petrolatum jelly			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-400
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1 g in 1 g
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:67777-400-01	12 in 1 CASE	

1		6 in 1 BOX		
1		113.4 g in 1 TUBE		
2	NDC:67777-400-02	12 in 1 CASE		
2		6 in 1 BOX		
2		28.35 g in 1 TUBE		
3	NDC:67777-400-03	12 in 1 CASE		
3		6 in 1 BOX		
3		58.7 g in 1 TUBE		
4	NDC:67777-400-04	12 in 1 CASE		
4		425.2 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/23/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic PharmaIndia Private Limited		918531450	manufacture(67777-400)

Establishment

Name	Address	ID/FEI	Business Operations
Amar Remedies Limited		915839811	manufacture(67777-400)

Revised: 12/2012

Dynarex Corporation