

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.

White Petrolatum

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

Principal Display Panel

petrolatum_jelly.jpg



PETROLATUM

petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-211
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	Marketing End Date
1	NDC:67777-211-01	144 in 1 BOX		
1		5 g in 1 PACKET		
2	NDC:67777-211-02	425.2 g in 1 JAR		
3	NDC:67777-211-03	1 in 1 BOX		
3		28.35 g in 1 TUBE		
4	NDC:67777-211-07	6 in 1 BOX		
4		113.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/31/2010	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Choice Laboratories		650070394	manufacture(67777-211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(67777-211)

Revised: 4/2013

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