

PETROLATUM- petrolatum jelly
Choice Laboratories Limited

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

CHPetrolatum.jpg

Reorder No. 1145
NDC # 63174-211-07

Drug Facts		Drug Facts (continued)	
Active Ingredient White Petrolatum USP (100% w/w)	Purpose Skin Protectant	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.	Manufactured by: Choice Laboratories Limited State Highway, Brahmanwada Ahmedabad, Gujurat, 384215 India Made in India  6 16784 11451 4
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

petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63174-211
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:63174-211-07	113.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63174-211-03	28.35 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:63174-211-02	425.2 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/18/2015	

Labeler - Choice Laboratories Limited (650070394)

Establishment

Name	Address	ID/FEI	Business Operations
Choice Laboratories Limited		650070394	manufacture(63174-211)

Revised: 5/2015

Choice Laboratories Limited