

ROYAL PETROLEUM JELLY- petrolatum jelly

Royal Exports

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.

Active Ingredient

White petrolatum (100 % w/w)

Purpose

Skin Protectant

Uses

- temporarily protects minor cuts, scrapes, burns and sunburn
- temporarily protects and helps relieve chapped or cracked skin
- helps protect from the drying effects of wind and cold weather
- helps treat and prevent diaper rash
- helps seal out wetness

Warnings

FOR EXTERNAL USE ONLY

When using this product

Do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within 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

Apply as needed

None

NDC : 51328-1010-5

ROYAL

PETROLEUM JELLY

~ 100% PURE ~

NET WT. 13 OZ (368g)

Drug Facts		Drug Facts (continued)
Active Ingredient White Petroleum 100%	Purpose Skin Protectant	Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.
Uses •temporarily protects minor cuts, scrapes, burns •temporarily protects and helps relieve chapped or cracked skin. • helps protect from the drying effects of wind and cold weather. • helps treat and prevent diaper rash • helps seal out wetness		
Warnings For External Use Only •When using this product do not get into eyes. Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days. Do not use on • deep or puncture wounds • animal bites • serious burns		Directions •Apply as needed.
		Lot No.: 28 Exp.Dt.: 09/2019
		
		CODE MH/COS/KD/C-275 Dist by Pioneer Assoc. Brooklyn, NY 11206 Product of India

NDC : 51328-1010-3

ROYAL

PETROLEUM JELLY

~ 100% PURE ~

NET WT. 8 OZ (226g)

Drug Facts		Drug Facts (continued)
Active Ingredient White Petroleum 100%	Purpose Skin Protectant	Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.
Uses •temporarily protects minor cuts, scrapes, burns •temporarily protects and helps relieve chapped or cracked skin. • helps protect from the drying effects of wind and cold weather. • helps treat and prevent diaper rash • helps seal out wetness		
Warnings For External Use Only •When using this product do not get into eyes. Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days. Do not use on • deep or puncture wounds • animal bites • serious burns		Directions •Apply as needed.
		Lot No.: 28 Exp.Dt.: 09/2019
		
		CODE MH/COS/KD/C-275 Dist by Pioneer Assoc. Brooklyn, NY 11206 Product of India

ROYAL PETROLEUM JELLY

petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51328-10 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	100 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:51328-1010-3	226 g in 1 JAR; Type 0: Not a Combination Product	10/10/2016	
2	NDC:51328-1010-5	368 g in 1 JAR; Type 0: Not a Combination Product	10/10/2016	
3	NDC:51328-1010-4	283 g in 1 JAR; Type 0: Not a Combination Product	10/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/10/2016	

Labeler - Royal Exports (650621381)

Revised: 11/2018

Royal Exports