

ROYAL PETROLEUM JELLY WITH BABY SCENT- white 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 (99.9% w/w)

Purpose

Skin Protectant

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

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Apply as needed

Inactive Ingredient

Fragrance

Package Label



ROYAL PETROLEUM JELLY WITH BABY SCENT

white petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51328-1020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.9 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:51328-1020-3	226 g in 1 JAR; Type 0: Not a Combination Product	10/10/2016	
2	NDC:51328-1020-5	368 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)

Establishment

Name	Address	ID/FEI	Business Operations
Royal Exports		650621381	manufacture(51328-1020)

Revised: 1/2020

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