AMORAY PETROLATUM JELLY ORIGINAL- petrolatum jelly My Imports USA LLC

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.

AMORAY ORIGINAL PETROLEUM JELLY

Active Ingredient

White Petrolatum (99.5% 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 for more than 7 days or clean up and occur again 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

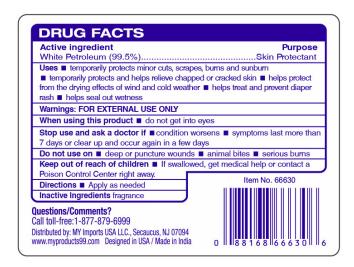
• Apply as needed

Inactive Ingredient

Fragrance

Package Label





AMORAY PETROLATUM JELLY ORIGINAL

petrolatum jelly

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51628-6663

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) PETROLATUM 99.5 g in 100 g

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

Packaging

-111						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:51628-6663-3	369 g in 1 JAR; Type 0: Not a Combination Product	04/07/2019			
	2 NDC:51628-6663-0	170 g in 1 JAR; Type 0: Not a Combination Product	04/07/2019			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/07/2019	

Revised: 4/2019 My Imports USA LLC