## CLASSIC CARE PETROLEUM- petrolatum jelly FDN Enterprises, 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.

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Classic Care® Petroleum Jelly

**Drug Facts** 

## **Active Ingredients**

Petrolatum USP 100%

## **Purpose**

Skin Protectant

#### Uses

- temporarily protects minor:
  - cuts
  - scrapes
  - burns
- temporarily protects and helps relieve chapped or cracked skin and lips
- helps protect from the drying effects of wind and cold weather.

## Warnings

For external use only

## When using this product

• do not get into eyes.

#### Do not use on

- deep or puncture wounds
- laceration or infections
- animal bites
- serious burns

**Stop use and ask doctor** if condition lasts more than 7 days.

**Keep out of reach of children** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

apply as needed

Distributed by: FDN Enterprises, LLC. Opa Locka, FL 33054.

## PRINCIPAL DISPLAY PANEL - 510 g Jar Label

Unscented

Classic Care®

PETROLEUM JELLY

Skin Protectant

Net Wt 18 Oz (510g)

Unscented / Sin perfume / Sans perfum

# Classic Care®

## PETROLEUM JELLY / VASELINA / VASELINE

Skin Protectant / Protector de la piel / Protection de la peau

Net Wt 18 Oz (510g) / Peso neto 510g | Poids net 5109

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SKU# 14099918

Made In India

## petrolatum jelly

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60691-126

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

## **Packaging**

#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:60691-126-34	510 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
ı	OTC MONOGRAPH FINAL	part347	05/30/2011	
ı				

## Labeler - FDN Enterprises, LLC (965743867)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vikshara Trading & Investments Ltd		675920690	MANUFACTURE(60691-126)	

Revised: 5/2015 FDN Enterprises, LLC