

**CLASSIC CARE PETROLEUM- white 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**

White Petrolatum USP (99.9%)

**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

**Inactive ingredients**

Water

**PETROLEUM JELLY/ VASELINE**

**Unscented**

**Distributed by:**

**FDN Enterprises, LLC.**

**Opa Locka, FL 33054.**

**Made In India**

**Packaging**

**Classic Care<sup>®</sup>**

**PETROLEUM JELLY / VASELINA / VASELINE**

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

**Unscented**

Net Wt 18 Oz (510g)

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SKU# 14099918

Made In India

GUJ/COS/GC/32/1374



## CLASSIC CARE PETROLEUM

white petrolatum jelly

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60691-130
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.9 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60691-130-01	1 in 1 BOX	09/15/2021	
1		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
OTC monograph final	part347	09/15/2021	

**Labeler** - FDN Enterprises, LLC (965743867)

## Establishment

Name	Address	ID/FEI	Business Operations
ORCHID LIFESCIENCES		675474890	manufacture(60691-130)

Revised: 9/2021

FDN Enterprises, LLC