CLASSIC CARE BABY- 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.

Classic Care ® Baby

Drug Facts

Active Ingredients

White Petrolatum USP 99.8%

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

Fragrance

PRINCIPAL DISPLAY PANEL - 368 g Bottle Label

Classic Care ®

Soft and gentle as a mother's embrace.

Baby Petroleum Jelly

NET WT 13 OZ (368g)

Classic Care®

Soft and gentle as a mother's embrace. Suave y delicado como la caricia de mamá Doux et tendre comme les bras d'une maman.

Baby Petroleum Jelly Vaselina para bebés Vaseline pour bébé

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CLASSIC CARE BABY

petrolatum jelly

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:60691-123

Route of Administration TOPICAL

Active Ingredient/Active Moiety

п	, g		
ı	Ingredient Name	Basis of Strength	Strength
ı	Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petro latum	998 mg in 1 g

Packaging

ı					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:60691-123-31	368 g in 1 CONTAINER			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	05/30/2011	

Labeler - FDN Enterprises, LLC (965743867)

Establishment					
Name	Address	ID/FEI	Business Operations		
Vikshara Trading & Investment Ltd		675920690	MANUFACTURE(60691-123)		

Revised: 12/2013 FDN Enterprises, LLC