

UNIVERSAL COCOA BUTTER SCENT PETROLEUM- white petroleum jelly
Universal Distribution Center 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.

UNIVERSAL COCOA BUTTER SCENT PETROLEUM

Active ingredient

White Petrolatum USP (99.9 %)

Purpose

Skin Protectant

Uses

- For the temporary protection of minor cuts, scrapes, burns and sunburn.
- Helps to temporarily protect chafed, chapped, cracked or windburned skin and lips.

Warnings

For External Use Only.

Do not use over deep or puncture wounds, infections or lacerations. Ask a doctor.

When using this product avoid contact with eyes.

Stop use and ask doctor if condition worsens or does not improve within 7 days.

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

Directions

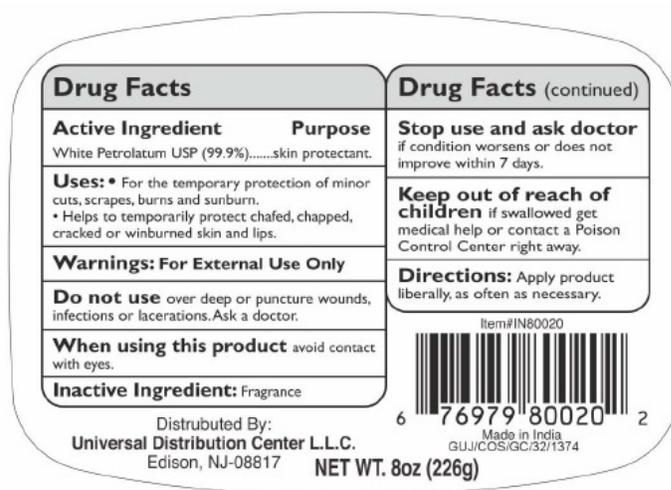
Apply product as liberally, as often as necessary.

Inactive ingredients

Fragrance

PRINCIPAL DISPLAY PANEL

Universal Cocoa Butter Scent Petroleum
Jelly
Net Wt. 8 OZ (226 g)



UNIVERSAL COCOA BUTTER SCENT PETROLEUM

white petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-119
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:52000-119-01	170 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
2	NDC:52000-119-02	226 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
3	NDC:52000-119-03	368 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	
4	NDC:52000-119-04	510 g in 1 JAR; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part347	11/01/2019	
---------------------	---------	------------	--

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Jell Pharmaceuticals Pvt Ltd (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt Ltd		726025211	manufacture(52000-119)

Revised: 11/2022

Universal Distribution Center LLC