

PURE PETROLEUM - white petroleum jelly
Pan Aromas 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.

PURE PETROLEUM JELLY

Active ingredient

White petrolatum USP (100 %)

Purpose

Skin protectant

Uses

- For the temporary protection of minor cuts, scraps, 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 a doctor

if condition worsens or does not improve after 7 days.

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Directions

Apply liberally, as often as necessary.

Inactive ingredients

None

PRINCIPAL DISPLAY PANEL

PURE PETROLEUM JELLY

NET WT. 8 OZ (226 g)



Drug Facts

Ingredient:

White petrolatum USP (100%).....

Purpose:

Skin protectant

USES: Pan Aromas Petroleum Jelly 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 • Avoid contact with eyes • Stop use and ask a doctor if condition worsens or does not improve after 7 days • Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Apply liberally, as often as necessary.

MADE IN INDIA

DNH/C-92



Manufactured for
Pan Aromas LLC.
Green Brook
NJ - 08812

white petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50346-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50346-001-01	100 g in 1 JAR		
2	NDC:50346-001-02	113 g in 1 JAR		
3	NDC:50346-001-03	142 g in 1 JAR		
4	NDC:50346-001-04	170 g in 1 JAR		
5	NDC:50346-001-05	198 g in 1 JAR		
6	NDC:50346-001-06	226 g in 1 JAR		
7	NDC:50346-001-07	255 g in 1 JAR		
8	NDC:50346-001-08	283 g in 1 JAR		
9	NDC:50346-001-09	368 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/26/2012	

Labeler - Pan Aromas LLC (078451131)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture

Revised: 5/2012

Pan Aromas LLC