

BABY FRESH SCENT 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.

BABY FRESH SCENT PETROLEUM JELLY

Active ingredient

White petrolatum USP (99.9 %)

Purpose

Skin protectant

Uses

- Ideal for your baby's skin care needs
- Restores smooth and healthy skin
- Helps to treat and prevent your baby's delicate skin from diaper rash
- It works to seal out wetness
- Helps to soothe dry, chapped, cracked or irritated skin and lips due to cold and wind

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

Cleanse and dry area, apply liberally, as often as necessary.

Inactive ingredients

Fragrance

PRINCIPAL DISPLAY PANEL

BABY FRESH SCENT

PETROLEUM JELLY

SKIN PROTECTANT FOR BABIES

NET WT. 8 OZ (226 g)



Drug Facts

Active Ingredient:

White petrolatum USP (99,9%).....

Purpose:

Skin protectant

USES: Pan Aromas Petroleum Jelly is ideal for your baby's skin care needs • Restores smooth and healthy skin • Helps to treat and prevent your baby's delicate skin from diaper rash • It works to seal out wetness • Helps to soothe dry, chapped, cracked or irritated skin and lips due to cold and wind.

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: Cleanse and dry area, apply liberally, as often as necessary.

Inactive Ingredient: Fragrance

MADE IN INDIA

DNH/C-92



Manufactured for
Pan Aromas LLC.
Green Brook
NJ - 08812

BABY FRESH SCENT PETROLEUM

white petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50346-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.99 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50346-002-01	100 g in 1 JAR		
2	NDC:50346-002-02	113 g in 1 JAR		
3	NDC:50346-002-03	142 g in 1 JAR		
4	NDC:50346-002-04	170 g in 1 JAR		
5	NDC:50346-002-05	198 g in 1 JAR		
6	NDC:50346-002-06	226 g in 1 JAR		
7	NDC:50346-002-07	255 g in 1 JAR		
8	NDC:50346-002-08	283 g in 1 JAR		
9	NDC:50346-002-09	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