# BABY PETROLATUM JELLY- petrolatum jelly SHIELD LINE 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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## **Active Ingredient**

White Petrolatum USP (99.9%)

## **Purpose**

Skin Protectant

#### Uses

- helps treat and prevent diaper rash
- helps seal out wetness

## Warnings: FOR EXTERNAL USE ONLY

#### Do not use on

- deep and punture wounds
- animal bites
- serious burns

### When using this product

• do not get into eyes

#### Stop Use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clean up and occur again in few days

## Keep out of reach of children

• if swallowed, get medical help or contact a Poison Control Center right away

#### Directions

• apply liberally to clean out diaper rash area

## Other Information

• Store at room temperature

## **Inactive Ingredient**

Fragrance



# **Drug Facts**

Active ingredient

Purpose

32-02032MSC-01

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Inactive Ingredients Fragrance

Manufactured for Shield Line LLC, Hackensack, NJ 07601 USA Made in India MSC-02062

#### BABY PETROLATUM JELLY

petrolatum jelly

#### **Product Information**

HUMAN OTC DRUG NDC:52410-0206 Product Type Item Code (Source)

Route of Administration	TOPICAL	
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Active Ingredient/Active Moiety			
Ingred	ent Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PET	TROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.9 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
1	NDC:52410-0206-2	226 g in 1 JAR; Type 0: Not a Combination Product	06/21/2016	
2	NDC:52410-0206-4	368 g in 1 JAR; Type 0: Not a Combination Product	06/21/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/21/2016	

## Labeler - SHIELD LINE LLC (078518916)

Revised: 6/2016 SHIELD LINE LLC