PERSONAL CARE PETROLEUM- petrolatum jelly Personal Care Products

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.

Personal Care Petroleum

Active ingredients White Petroleum 99.9%

Purpose skin protectant

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

Use helps prevent diaper rash

Warnings For external use only When using this product do not get into eyes See a doctor if condition worsens or lass more than 7 days Do not use on deep puncture wounds, animal bites, serious burns.

Directions

change and cleanse diaper area and allow to dry

apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged

Inactive ingredients fragrance



| Brug Facts | Drug Facts (continued) | | | |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--|--|--|
| Active Ingredients Purpose White Petroleum 90.9%.skin protectant | Overlights = change and cleanse diaper area, and allow to dry = apply product as | | | |
| Use helps prevent dia per rash | needed, with each diaper change, especially al bedtime and when exposure to wel | | | |
| Warnings | diapens may be prolonged | | | |
| For external use only | Inactive Ingredients tragrame. | | | |
| When using this product do not get into eyes | Distributed by: | | | |
| See a doctor if condition worsens or lasts more than 7 days | PERSONAL CARE PRODUCTS, LLC Troy, Michigan 48084 Made in India | | | |
| Do not use on 🔲 deep puncture wounds 🖩 animal bites 🖷 serious burns | | | | |
| Keep out of reach of children, 11 swallowed, gef medical help or confact a Poison Control Center right away | o 48155 90347 c | | | |

Personal Care 100% Pure Petroleum Jelly Baby Fresh scent Net wt. 6 oz (170g) Distributed by: Personal Care Products, LLC Troy, Michigan 48084

Made in India

 Personal care personal substration

 Product Information

 Product Type
 HUMAN OTC DRUG

 Route of Administration
 TOPICAL

| Active Ingredient/Active Moiety | | | | | | | | |
|--------------------------------------------------------------|------------------------------------------|----------------------|----------------------|-------------------|--------------------|----------------|--|--|
| Ingredient Name | | | В | Basis of Strengtl | | Strength | | |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | | | PET | PETROLATUM | | 170 g in 170 g | | |
| | | | | | | | | |
| | | | | | | | | |
| Packaging | | | | | | | | |
| # Item Code | Package Description | Marketing Start Date | | e Ma | Marketing End Date | | | |
| I NDC:29500-8030-2 | 170 g in 1 JAR | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Marketing Info | rmation | | | | | | | |
| | Application Number or Monograph Citation | | Marketing Start Date | | Marketing End Dat | | | |
| Marketing Category | reprication number of monogr | upn Chanon | inter the ding | | | | | |

Labeler - Personal Care Products (966155082)

Registrant - Personal Care Products (966155082)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|----------------------------|
| Jell Pharmaceuticals | | 726025211 | manufacture(29500-8030) |

Revised: 6/2012

Personal Care Products