

HEALTH SMART CREAMY PETROLEUM- petroleum jelly
Anicare Pharmaceuticals Pvt. Ltd

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.

Health Smart Creamy Petroleum Jelly

Active Ingredient

Petrolatum 30%

Purpose

Skin Protectant

Uses

- temporarily protects minor; cuts, scrapes or burns.
- temporarily protects and helps relieve chapped or cracked skin.
- helps protect from the drying effects of wind and cold weather.

Warnings

For external use only.

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 clear up and occur again within a few days.

Do not use on

- deep puncture wounds
- animal bites
- serious burns

Keep out of reach of children

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

Directions

apply as needed.

Inactive Ingredients

water (aqua), carbopol 940, stearic acid, glyceryl monostearate, mineral oil, cetearyl alcohol, GE125 emulsifying agent, methylparaben, propylparaben, triethanolamine, tocopheryl acetate.

PRINCIPAL DISPLAY PANEL

HEALTH SMART CREAMY PETROLEUM JELLY

NET WT. 4.5 OZ. (128G)

*Compare to Vaseline® Petroleum Jelly Cream



- Heals severely dry skin
- Fragrance Free
- Enriched with Vitamin E

Skin Protectant

Net Wt. 4.5 OZ (128g)

Drug Facts

Active ingredient: Petrolatum 30% **Purpose:** Skin Protectant

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Warnings

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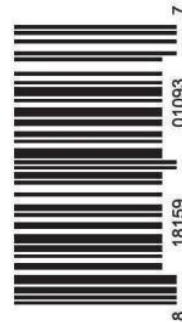
Do not use on deep puncture wounds, animal bites, serious burns

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HEALTH SMART CREAMY PETROLEUM

petroleum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:470 46-166
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6 H12BN9 U) (PETROLATUM - UNII:4T6 H12BN9 U)	PETROLATUM	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-166-01	128 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/10/2014	

Labeler - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment			
Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-166)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd