HEALTH SMART CREAMY COCOA BUTTER 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 Cocoa Butter 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, fragrance, cocoa butter.

PRINCIPAL DISPLAY PANEL

HEALTH SMART CREAMY COCOA BUTTER PETROLEUM JELLY

NET WT. 4.5 OZ. (128G)



Drug Facts

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MADE IN INDIA • HS-01083
DISTRIBUTED BY:

SOUTHFIELD, MI 48075

*This product is not manufactured or distributed by Unilever, owners of the registered trademark Vaseline®

HEALTH SMART CREAMY COCOA BUTTER PETROLEUM

petroleum jelly

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:47046-165

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)
PETROLATUM 30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLPARABEN (UNII: A218 C7H19 T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCOA BUTTER (UNII: 512OYT1CRR)	

l	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:47046-165-01	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	0 1/10/20 14				

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 (47046-165)		

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd