# HEALTH SMART CREAMY COCOA BUTTER PETROLEUM- petroleum jelly International Wholesale Inc dba Home Smart 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.

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### **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)



## **HEALTH SMART CREAMY COCOA BUTTER PETROLEUM**

petroleum jelly

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:52862-019 Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of 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: 2300U9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 903K93S3TK)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCOA BUTTER (UNII: 5120YT1CRR)	

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-019-	128 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	

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

## Labeler - International Wholesale Inc dba Home Smart Products (161872676)

## Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52862-019)		

Revised: 1/2022 International Wholesale Inc dba Home Smart Products