

LUCKY SUPER SOFT COCOA BUTTER- white petrolatum cream
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.

super soft cream

Active ingredient

White petrolatum USP (30%)

Purpose

Skin protectant

Uses

■ temporarily protects minor ■ cuts ■ scrapes ■ burns ■ temporarily protects and helps relieve chapped or cracked skin ■ helps prevent and 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 in a few days

Do not use on

■ deep or 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, cetearyl alcohol, cetareth 20, glycerin, mineral oil, fragrance, benzyl alcohol, methylchloroisothaizolinone, methylisothaizolinone, titanium dioxide, citric acid, tocopheryl acetate, theobroma cacao seed butter, FDC yellow no 6, DC red no 33, FDC yellow no 5, FDC blue no 1

Package Label



LUCKY SUPER SOFT COCOA BUTTER

white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47046-170
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: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	

BENZYL ALCOHOL (UNII: LKG8494WBH)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
COCOA BUTTER (UNII: 512OYT1CRR)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-170-01	127 g in 1 TUBE; Type 0: Not a Combination Product	03/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/01/2015	

Labeler - Anicare Pharmaceuticals Pvt. Ltd. (916837425)

Registrant - Anicare Pharmaceuticals Pvt. Ltd. (916837425)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd.