

BUDPAK VITAMIN A AND D- vitamin a and d cream

Budpak Inc.

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.

Budpak Vitamin A&D Cream

Active Ingredients

Vitamin A 181.8 IU

Vitamin D 1200 IU

Purpose

Skin protectant

Uses

- helps prevent diaper rash
- heals dry, flaky and chafed skin
- soothes and protects minor cuts and burns

Warnings

For external use only

Do not use in eyes

- not for extensive burns or serious cuts, consult a physician

Stop use and ask a doctor if redness, irritation, swelling or pain persists or increases or if infection develops.

Keep out of reach of children.

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

Directions

- Apply generously and massage until absorbed. Repeat as necessary.

Other information

- Store at controlled room temperature 15°C to 30°C (59°F to 86°F). Lot No. & Exp.Date see crimp of tube.

Inactive ingredients

Cetyl Alcohol, DMDM Hydantoin, Glyceryl Monostearate, Methylparaben, Mineral Oil, Polysorbate 20, Propylparaben, Stearic Acid, Trisodium EDTA, and Water.

PRINCIPAL DISPLAY PANEL

Budpak Vitamin A&D Cream

NET WT 1 OZ (28 g)



BUDPAK VITAMIN A AND D

vitamin a and d cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:27293-036

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	181.8 [iU] in 1 g
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	1200 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-036-28	28 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	04/01/2015	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-036)