AMERIDERM VITAMIN A D- white petrolatum ointment Shield Line LLC

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.

ALL-160 NEW

Active Ingredient

White petrolatum USP (93% w/w)

Purpose

Skin Protection

Uses

■ Helps treat and prevent diaper rash ■ helps seal out wetness ■ temporarily protects minor ■ cuts ■ scrapes ■ burns ■ temporarily helps protect and relieve chapped and cracked skin or lips ■ helps prevent and protect from the drying effects of wind and cold weather ■ helps prevent and protect chafed skin or minor skin irritations associated with diaper rash ■ with each diaper change, espicially at bedtime when exposure to wet diapers may be prolonged

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

For Skin Protection and Diaper rash ■ apply as needed

Additionally when using for Diaper Rash ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry

Other Information

■ store at 15-30C (59-86F) ■ avoid excessive heat and humidity

Inactive ingredients

lanolin, lavender fragrance, light mineral oil, paraffin, vitamin A, vitamin D

Package Label



AMERIDERM VITAMIN A D

white petrolatum ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52410-8037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	93 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
LANOLIN (UNII: 7EV65EAW6H)		
VITAMIN A (UNII: 81G40H8B0T)		
VITAMIN D (UNII: 9 VU1KI44GP)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:52410-8037-2	100 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2018	
2 NDC:52410-8037-3	425 g in 1 JAR; Type 0: Not a Combination Product	07/01/2018	

Marketing Infor	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part347	11/0 1/20 14

Labeler - Shield Line LLC (078518916)

Revised: 12/2020 Shield Line LLC