

VITAMIN A AND D- vitamin a and d ointment
GERITREX 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.

Vitamin A&D Ointment

Drug Facts

Active Ingredient

White Petrolatum 95%

Purpose

A Skin protectant

Uses

For the temporary protection of minor cuts, scrapes, burns. Protects chafed skin

Warnings

FOR EXTERNAL USE ONLY.

When using this product: Avoid contact with eyes.

DO NOT apply over deep or punctured wounds, infections or lacerations

IF CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 7 DAYS STOP USE AND CONSULT A PHYSICIAN.

KEEP OUT OF REACH OF CHILDREN.

In the event of accidental ingestion contact a Poison Control Center right away.

Directions

Cleanse area with mild soap and water. Apply liberally as often as necessary.

Storage

- Store at Controlled Room Temperature 15°-30°C (59°-86°F).

Inactive ingredients

Cod Liver Oil, Lanolin, Mineral Oil, Paraffin Wax, Phenoxyethanol, Vitamin A and Vitamin D

Label

NDC 54162-000-04

Vitamin A&D Ointment

Skin Protectant

NET WT. 4oz (113g)



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AD04



Distributed by Geritrex, LLC
40 Commercial Ave
Middletown, NY 10941
1-800-736-3437
www.geritrex.com

UNVARNISH 7 mm

NDC 54162-000-02



Vitamin A&D ointment

NET WT. 56g(2oz.)

START 5 mm



Drug Facts

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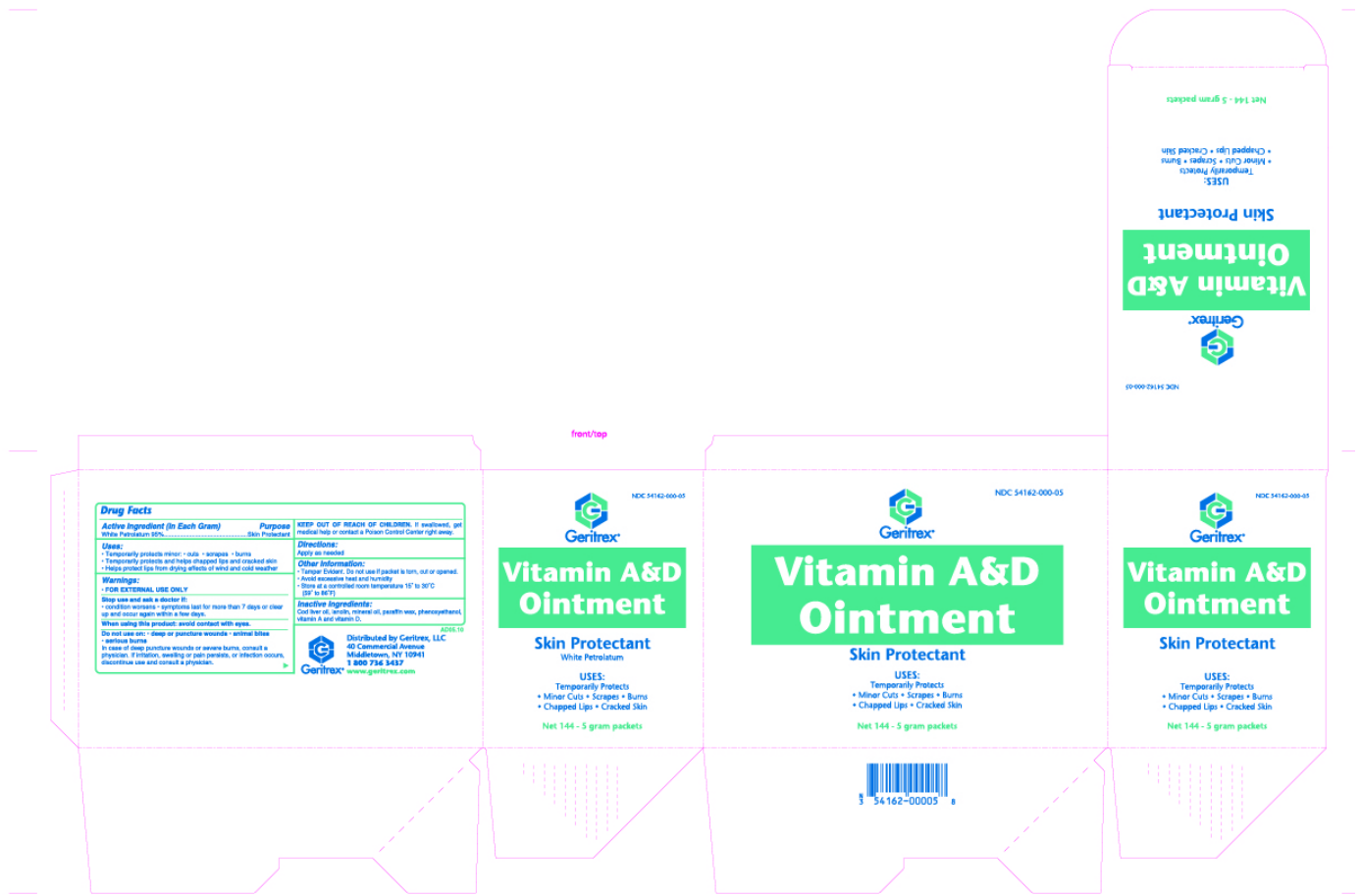
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ADO2-11



VITAMIN A AND D

vitamin a and d ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30.8 g in 56 g

Inactive Ingredients

Ingredient Name	Strength
COD LIVER OIL (UNII: BBL281NWF6G)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1K144GP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-000-04	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	
2	NDC:54162-000-02	56 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:54162-000-05	5 g in 1 POUCH; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2018	

Labeler - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-000)

Revised: 10/2018

GERITREX LLC