

A AND D PLUS E- vitamin a, d, and e ointment ointment
Gentell, 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.

A&D+E Ointment

Petrolatum 99.85%

Skin Protectant

Uses

temporarily protects minor:

- cuts
- scrapes
- burns

temporarily protects and helps relieve chapped, chafed, or cracked skin and lips

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.

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- animal bites
- serious burns

Keep out of reach of children.

For external use only

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

Directions

- apply as needed

apply as needed

Other information

store between 20°C to 25°C (68°F to 77°F)

avoid direct sunlight

Inactive ingredients

medium chain triglyceride oil, vitamin A palmitate, vitamin D₃, vitamin E (alpha-tocopherol)

Questions?

Call 800-840-9041 Monday through Friday 9:00 AM to 5:00 PM EST

Gentell We make it better

GEN-23450

A&D+E Ointment

Skin Protectant

13 oz. (369 g)

Gentell 2701 Bartram Road, Bristol, PA 19007 www.gentell.com

The image shows the product packaging for Gentell A&D+E Ointment. On the left is a box with the Gentell logo and the text 'A&D+E Ointment SKIN PROTECTANT 13 oz. (369g)'. To the right is a detailed Drug Facts label. The label includes sections for Active ingredient (Petrolatum 99.85%), Purpose (Skin Protectant), Uses (temporarily protects minor cuts, scrapes, burns, and helps relieve chapped, chafed, or cracked skin and lips), Warnings (For external use only, do not get into eyes), Do not use on (deep puncture wounds, animal bites, serious burns), Directions (apply as needed), Other information (store between 20°C to 25°C, avoid direct sunlight), Inactive ingredients (medium chain triglyceride oil, vitamin A palmitate, vitamin D₃, vitamin E), and Questions? (Call 800-840-9041). A barcode is also present with the number 61554 23450 2. A vertical 'Made in USA' label is on the right side of the packaging.

A AND D PLUS E

vitamin a, d, and e ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61554-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.9985 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
VITAMIN D (UNII: 9VU1KI44GP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61554-200-01	56.7 g in 1 TUBE; Type 0: Not a Combination Product	11/03/2014	
2	NDC:61554-200-02	113.4 g in 1 TUBE; Type 0: Not a Combination Product	11/03/2014	
3	NDC:61554-200-03	368.5 g in 1 JAR; Type 0: Not a Combination Product	11/03/2014	
4	NDC:61554-200-04	453.6 g in 1 JAR; Type 0: Not a Combination Product	11/03/2014	
5	NDC:61554-200-05	567 g in 1 JAR; Type 0: Not a Combination Product	11/03/2014	
6	NDC:61554-200-06	5 g in 1 PACKET; Type 0: Not a Combination Product	11/03/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/03/2014	

Labeler - Gentell, Inc. (170967876)

Establishment

Name	Address	ID/FEI	Business Operations
Gentell, Inc.		170967876	manufacture(61554-200)

Revised: 11/2020

Gentell, Inc.