

ALOE VESTA PROTECTIVE BARRIER - petrolatum spray
ConvaTec, 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.

Drug Facts

Active Ingredient

Petrolatum 36%

Purpose

Skin Protectant

Uses

- Temporarily protects minor
 - cuts
 - scrapes
 - burns.
-
- Temporarily protects and helps relieve chapped or cracked skin.
 - Helps treat and prevent diaper rash.
 - Protects minor skin irritation associated with diaper rash and helps seal out wetness.

Warnings

For external use only.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns.

When using this product

- avoid spraying in eyes
- do not intentionally inhale.

Stop use and see a doctor if

condition lasts more than 7 days.

Keep out of reach of children.

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

Flammable

Contents under pressure

- Keep away from heat, sparks, and open flame.
- Do not puncture or incinerate container.

- Exposure to temperatures above 120°F may cause bursting.

Directions

Do not overspray. Shake before use. Hold can 4-6 inches from skin and spray.

For skin protection

- Apply a thin continuous coating as needed.

For diaper rash

- Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply as needed, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged.


Other Information

Store at 15°C - 30°C (59°F - 86°F).


Inactive Ingredients

Hexamethyldisiloxane, Softisan 649, Mineral Oil, Aloe Extract.

PRINCIPAL DISPLAY PANEL

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For all ages. © 2008 ConvaTec Inc. ®/™ indicates a trademark of ConvaTec Inc. Manufactured for:  ConvaTec Inc. Skillman, NJ 08558 1-800-422-8811	
  7 68455 10865 7 CSX1876A Case Order No. 413401 ALOE VESTA™	

NDC 43553-4134-01

 **ConvaTec**

Protective Barrier Spray **3**

PROTECT

SKIN PROTECTANT

Shake before use

Soothes irritated skin
For weepy, denuded skin
Apply from any angle
Easy to remove

NET WT. 2.1 oz. (60g)

NDC 43553-4134-1

ConvaTec

ALOE VESTA™

Protective Barrier Spray 3

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CSX1876A Case Order No. 413401

ALOE VESTA PROTECTIVE BARRIER

petrolatum spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43553-4134
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	360 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
HEXAMETHYLDISILOXANE (UNII: D7M4659BPU)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color	white (Off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43553-4134-1	60 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/13/2005	

Labeler - ConvaTec, Inc. (947989757)**Registrant** - ConvaTec, Inc. (947989757)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurena		355607748	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
ConvaTec, Inc.		947989757	analysis

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ConvaTec, Inc.