

GALENTIC VITAMIN A D- petrolatum ointment
Galentic Pharma (India) Private Limited

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.

Galentic Vitamin A D

Active Ingredient	Purpose
White Petrolatum USP (76%)	Skin Protectant

Purpose:

- Helps treat and prevent diaper rash
- Helps seal out wetness

- Temporarily protects minor * cuts * scrapes * burns
- Temporarily helps protect and help relieve chapped and cracked skin and 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, especially at bedtime when exposure to wet diapers may be prolonged

Warnings:

For External Use Only

When using this product:

- Do not get in eyes

Stop use and ask a doctor if:

- If condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days

Do not use:

Do not use:

- Deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

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

Directions for diaper rash:

- Change wet and soiled diapers promptly
- Cleanse the diaper area and allow to dry
- Apply as needed

Other information:

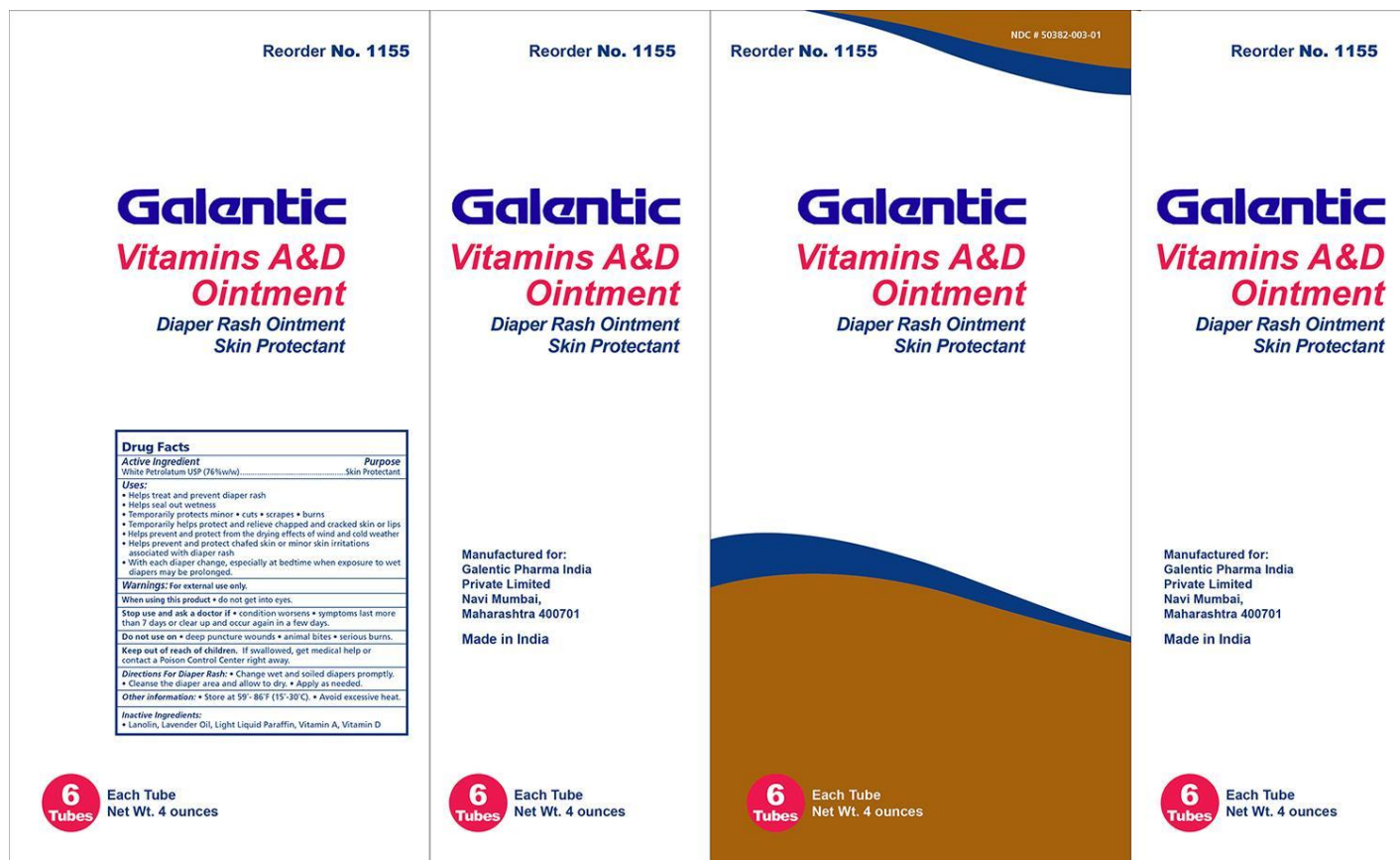
- Store at room temperature 15 deg C to 30 deg C 59 deg F to 86 deg F
- Avoid excessive heat

Inactive Ingredients:

Inactive Ingredients: Light Liquid Parafin, Vitamin A, Vitamin D

Principal Display Panel

Galentic Vit AD.jpg



GALENTIC VITAMIN A D

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	.76 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-003-01	113.4 g in 1 TUBE		
2	NDC:50382-003-02	425.25 g in 1 JAR		
3	NDC:50382-003-03	28.35 g in 1 TUBE		
4	NDC:50382-003-04	56.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/06/2013	

Labeler - Galentic Pharma (India) Private Limited (918531450)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		918531450	manufacture(50382-003)

Revised: 8/2013

Galentic Pharma (India) Private Limited