

JELL WITH VITAMIN A D- lanolin, petrolatum ointment
Jell Pharmaceuticals Pvt Ltd.

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

Active Ingredient

Lanolin 15.5%

Petrolatum 53.4%

Purpose

Diaper rash ointment

Skin protectant

Uses

■ helps treat and prevent diaper rash ■ temporarily protects minor cuts, scrapes and burns ■ temporarily protects and relieve chapped, chafed or cracked skin or lips ■ protects chafed skin due to diaper rash and helps seal out wetness

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 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 protectant use: ■ apply as needed ■ for diaper rash: ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

■ store at 20 to 25C (68-77F) ■ do not use if tube seal under cap is broken, missing or if tube tip is cut prior to opening

Inactive ingredients

cod liver oil (contains vitamin A and vitamin D), fragrance, light mineral oil, microcrystalline wax, paraffin

Package Label

50 mm Dia.

10 mm Sealing & Non Lacquer Area

7 2

125.0 mm Tube Length From Shoulder

Vitamin A&D Ointment

• helps prevent and treat diaper rash
• forms a protective barrier to help seal out wetness
• use at every diaper change

diaper rash ointment & skin protectant
• lanolin 15.5% • petrolatum 53.4%

NET WT 4.07 (113 g)

Drug Facts

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Lanolin 15.5%.....	Diaper rash ointment
Petrolatum 53.4%.....	Skin protectant

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- temporarily protects minor:
 - cuts ■ scrapes ■ burns
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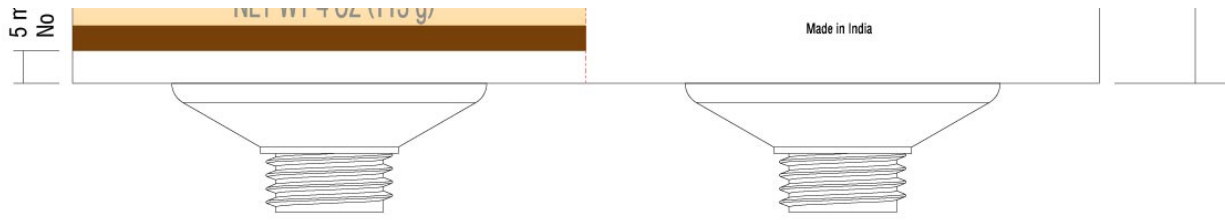
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- for diaper rash use: ■ change wet and soiled diapers promptly ■ cleanse the diaper area, and allow to dry ■ apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

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JELL WITH VITAMIN A D

lanolin, petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30400-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	53.4 g in 100 g
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	15.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
COD LIVER OIL (UNII: BBL281NWFQ)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30400-215-20	1 in 1 BOX	01/12/2022	
1	NDC:30400-215-02	56.6 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:30400-215-10	1 in 1 BOX	01/12/2022	
2	NDC:30400-215-01	28.3 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:30400-215-30	1 in 1 BOX	01/12/2022	
3	NDC:30400-215-03	85 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:30400-215-40	1 in 1 BOX	01/12/2022	
4	NDC:30400-215-04	113.3 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/12/2022	

Labeler - Jell Pharmaceuticals Pvt Ltd. (726025211)

Registrant - Jell Pharmaceuticals Pvt Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(30400-215)

Revised: 3/2022

Jell Pharmaceuticals Pvt Ltd.