

GALENTIC HYDROGEL- glycerin gel
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's Moisturizing Wound Hydrogel

Active Ingredient

Glycerin 20.0%

Purpose

Skin Protectant

• **USES**

Temporarily protects minor

- Cuts
- Scrapes
- Burns

• **WARNINGS**

For external use only

• **DO NOT USE ON**

- Deep or puncture wounds
- Animal bites
- Serious burns

• **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 a few days

• **KEEP OUT OF REACH OF CHILDREN**

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

• **DIRECTIONS**

- Apply as needed.
- Children under 6 months: Ask a doctor

• **OTHER INFORMATION**

Store at room temperature

• **INACTIVE INGREDIENT**

Allantoin, Aloe Barbadensis gel, Diazolidinyl urea, Methylparaben, PEG-4 Oliviate, PEG-60 Hydrogenated castor oil, Propylene glycol, Propylparaben, Purified water, Sodium polyacrylate, Tetrasodium EDTA, Tocopheryl acetate

Manufactured by : **Galentic Pharma (India) Pvt. Ltd.**, Plot No. 5-B & 5-C,
Sector III, Kandla Special Economic Zone, Gandhidham-370 230, Gujrat. India

PRINCIPAL DISPLAY PANEL - 84.7 g Tube Label

Galentic's
Moisturizing Wound Hydrogel

Galentic

Net Wt. 3 oz. (84.7 g)

- *With Vitamin E & Aloe Vera*
- *Clean and Greaseless*

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Drug Facts	Purpose
Active Ingredient	Glycerin 20% Skin Protectant
Uses	Temporarily protects minor • cuts • scrapes • burns
Warnings	
For External Use Only	
Do not use on	• deep or puncture wounds • animal bites • serious burns
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
Keep out of reach of children.	if swallowed, get medical help or contact a Poison Control Center right away.
Directions	• Apply as needed.
	• Children under 6 months: Ask a doctor
Other information	Store at room temperature
Inactive Ingredients	Purified Water, Aloe Barbardensis Gel, Sodium Polyacrylate, Propylparaben, Methyparaben, Diazolinyl Urea, Propylene Glycol, PEG-60 Hydrogenated Castor Oil, PEG-4 Oliveate, Tetrasodium EDTA, Allantoin, Tocopheryl Acetate
PATIENT NAME:	ROOM #

NDC # 50382-013-15

GUJ/DRUGS/G/25/2134

Made in India

GALENTIC HYDROGEL

glycerin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)		GLYCERIN	20 g in 100 g	
Inactive Ingredients				
Ingredient Name				Strength
ALLANTOIN (UNII: 344S277G0Z)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
EDETATE SODIUM (UNII: MP1J8420LU)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-013-15	24 in 1 CASE	04/14/2014	
1		84.7 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	part346	04/14/2014		

Labeler - Galentic Pharma (India) Private Limited (915110464)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		650970176	ANALYSIS(50382-013) , manufacture(50382-013) , PACK(50382-013) , REPACK(50382-013) , STERILIZE(50382-013)

Revised: 6/2018

Galentic Pharma (India) Private Limited