

DERMA GLIDE- glycerin gel
Pella Pharmaceuticals Co. Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Derma Glide Gel

Forms and Presentation

Gel: Tube, 75 g

Active Ingredients

Glycerin

Inactive Ingredients

Aqua, Propylene Glycol, Hydroxyethylcellulose, Phenoxyethanol, Ethylhexylglycerin, Citric Acid.

Purpose

Personal Lubricant

Properties

Derma Glide gel is gentle, transparent, greaseless water based gel, matches the pH of the vagina.

Does not contain fragrances, colorant, parabens, and silicone oils.

Indication

Derma Glide gel is a personal lubricant for him and her to apply it onto intimate areas, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

Precuations

Keep out of reach of children

Warnings

- For topical use only.

- Avoid contact with the eyes.
- If discomfort or irritation or discomfort occurs, discontinue use immediately and consult a physician.
- In case of vaginal infection, consult your doctor before use.
- If you are pregnant consult your doctor before use.
- This Product is not a spermicide and cannot be used as a contraceptive, but it may slow sperm down, so if you are trying to have a baby, talk to your doctor before use.
- Very slippery on surfaces, clean spills immediately.

Contraindication

Hypersensitivity to any of the components

Side Effects

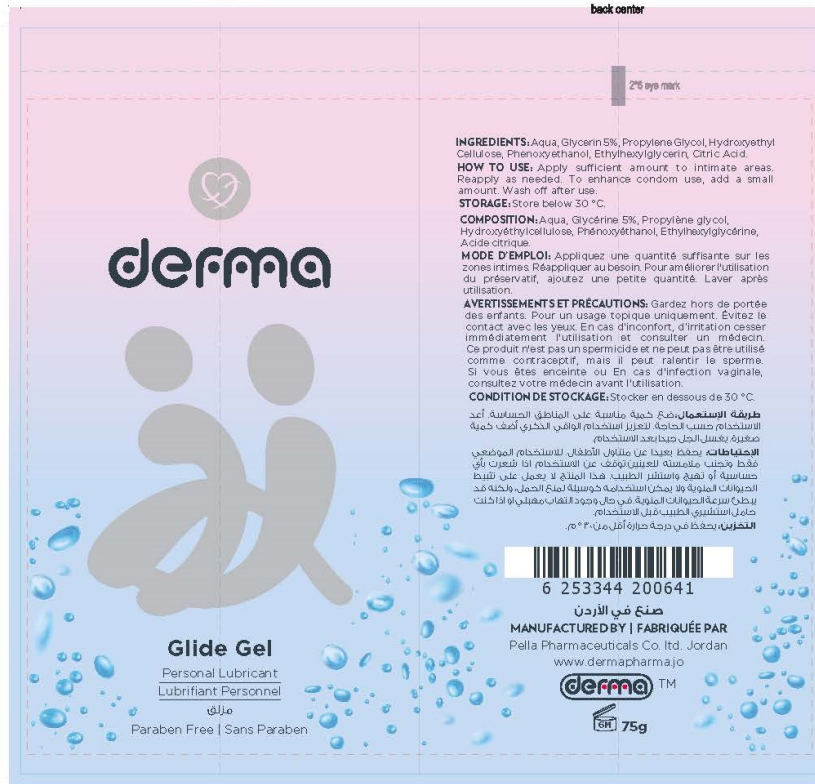
There are no known side effects

Dosage and Administration

Remove seal from tube opening before initial use. Apply sufficient amount to intimate areas. Reapply as needed. To enhance condom use, add a small amount to the inner and outer surfaces. Wash off after use.

Storage Conditions

Store below 30 °C



DERMA GLIDE

glycerin gel

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82160-641 |
| Route of Administration | VAGINAL, RECTAL, TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN | 50 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D) | |
| WATER (UNII: 059QF0KO0R) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82160-641-01 | 75 g in 1 TUBE; Type 0: Not a Combination Product | 05/31/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 05/31/2022 | |

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 6/2023

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