GLYZIGEN SINGLE DOSE INTIMATE GEL- glycerin gel
Catalysis, SL

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.

Glyzigen single dose Intimate Gel

Glycerin 0.5%.....Skin Protectant

- Stop use and ask a doctor if rash occurs
- Children under 6 months: ask a doctor

- Keep out of reach of children

- For external use only.
- Do not use on damaged or broken skin.
- When using this product keep our of the eyes. Rinse with water to remove.
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- Children under 6 months: as a doctor.

- Apply a small amount the intimate parts and gently wash. Rinse with water
- Maybe used as often as necessary

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+ 34 913456902 Monday to Friday: 9:00 am to 5:00 pm

- keep the product in a cool and dry place

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Water, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium Laureth Sulfosuccinate, Lactic Acid, Diazolidinyl Urea, Glycyrrhizinic,Acid, Sodium Benzoate, Potassium Sorbate, Phytosphingosine HCl, Parfum

Glyzigen Single Dose

GLYZIGEN SINGLE DOSE INTIMATE GEL

glycerin gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64539-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	12 mg in 1 mL
GLYCYRRHIZIN (UNII: 6FO62043WK)	0.1 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 mg in 1 mL
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	20 mg in 1 mL

DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	3 mg in 1 mL
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.01 mg in 1 mL
LACTIC ACID (UNII: 33X04XA5AT)	0.36 mg in 1 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.3 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 mg in 1 mL
WATER (UNII: 059QF0KO0R)	100 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-007-02	1 in 1 PACKAGE	01/11/2018	
1	NDC:64539-007-01	5 mL in 1 DOSE PACK; 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	01/11/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-007)

Revised: 1/2018 Catalysis, SL