

# GLYZIGEN GEL INTIMATE- 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.*

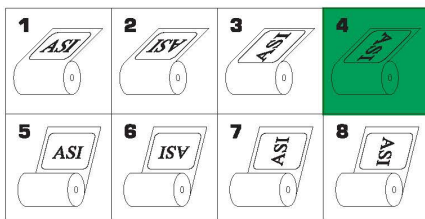
### Glyzigen Intimate Gel

Glycerin 0.5%.....Skin Protectant

grafiandia® s.l. Etiqueta\_GLIZIGEN\_Gel\_250\_Usa\_V1  
TALLERES GRÁFICOS

CLIENTE: CATALYSIS	CÓDIGO PRODUCTO:	Nº PEDIDO:	Nº REVISION: 1	FECHA: <b>24-6-2015</b>
Nº HOJA DE RUTA:	MEDIDAS: 200x45 mms	MATERIAL: Adhesivo polipropileno blanco	ACABADO:	
<b>TOTAL COLORES</b> 4 <b>CUATRICROMIA</b> ■ CIAN ■ MAGENTA ■ AMARILLO ■ NEGRO	 catalysis	<b>ESTAMPACION PELICULA</b>	OBSERVACIONES FOTOMECANICA:	
			OBSERVACIONES CLIENTE:	022-49809 EU-V.2

<p><b>DRUG FACTS</b></p> <p><b>Active ingredients</b> Glycerin 0.5% Purpose: Skin protectant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Helps to maintain the pH of the intimate parts in a natural way, cleanses the skin</li> <li>Maintains the natural microflora of the mucosae of the sexual organs</li> <li>Relieves all sort of irritation and redness caused by depilation, the use of sanitary pads, synthetic and/or tight underwear. Makes you feel clean and fresh all day</li> </ul> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>For external use only</li> <li>Do not use on damaged or broken skin</li> <li>Stop use and ask a Doctor if rash occurs</li> <li>Keep out of reach of children</li> </ul> <p><b>When using this product</b> Avoid contact with eyes Keep out of reach of children. In case of overdose get medical help or Contact a Poison Control Center right away.</p>	 <p><b>GLYZIGEN®</b> intimate gel Skin protectant</p> <p>e 250 g • 8.82 oz.</p> <p>Made in Spain Catalysis, S.L. Macarena, 14 28016 Madrid / SPAIN www.catalysis.es</p>	<p><b>DRUG FACTS</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Apply a small amount onto the intimate parts and gently wash. Rinse with water</li> <li>May be used as often as necessary</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Keep the product in a cool and dry place</li> </ul> <p><b>Inactive Ingredients</b> Aqua, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium PEG-5 Lauryl Citrate Sulfosuccinate-Sodium Lauryl Sulfate, Lactic Acid, Disazolidinyl Urea, Glycyrrhizinic Acid, Sodium Benzoate, Potassium Sorbate, Phosphoglycosine HCl, Parfum</p> <p><b>Questions or comments ?</b> +34 913436902 Monday to Friday: 9:00 am to 5:00 pm</p> <p><b>Temper evident: do not use if plastic in the pump of the bottle is broken or missing</b></p>
---	---	---



- 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.
- Stop use and ask a doctor if rash occurs.
- Keep out of reach of children
- 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

- Apply a small amount the intimate parts and gently wash. Rinse with water
- Maybe used as often as necessary
- Stop use and ask a doctor if rash occurs
- Children under 6 months: ask a doctor

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

- keep the product in a cool and dry place
- Apply a small amount the intimate parts and gently wash. Rinse with water
- Maybe used as often as necessary

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

Caja\_GLIZIGEN\_Gel\_250g\_USA\_V. 2



**GLIZIGEN®**

**intimate gel**  
Skin protectant  
topical use

**8.82 oz.**  
(250g)

Made in Spain by:  
**catalysis**  
Catalysis, S.L.  
Macarena, 14  
28016 Madrid • SPAIN / ESPAGNE  
www.catalysis.es

**DRUG FACTS**

Active ingredients	Purpose
Glycerin 0.5%	Skin protectant

**Uses**

- Helps to maintain the pH of the intimate parts in a natural way, cleanses the skin
- Maintain the natural microflora of the mucosae of the sexual organs.
- Relieves all sort of irritation and redness caused by depilation, the use of sanitary pads, synthetic and/or tight underwear. Makes you feel clean and fresh all day

**Warnings**

- For external use only
- Do not use on damaged or broken skin
- Stop use and ask a Doctor if rash occurs
- Keep out of reach of children

**When using this product**  
Avoid contact with eyes  
**Keep out of reach of children.** In case of overdose get medical help or Contact a Poison Control Center right away.

**Directions**

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

**Other information**

- Keep the product in a cool and dry place

**Inactive Ingredients**  
Aqua, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium PEG-3 Laurylsulfate Sulfosuccinate-Sodium Lauryl Sulfate, Lactic Acid, Diazolidinyl Urea, Glycyrrhizinic Acid, Sodium Benzoate, Potassium Sorbate, Phytosphingosine HCl, Parfum

**Questions or comments ?**  
+34 913456902 Monday to Friday: 9:00 am to 5:00 pm

**GLIZIGEN®**

**intimate gel**  
Skin protectant

**8.82 oz.**  
(250g)

*Temper evident: do not use if plastic in the pump of the bottle is broken or missing*

**DRUG FACTS**

Active ingredients	Purpose
Glycerin 0.5%	Skin protectant

**Uses**

- Helps to maintain the pH of the intimate parts in a natural way, cleanses the skin
- Maintain the natural microflora of the mucosae of the sexual organs.
- Relieves all sort of irritation and redness caused by depilation, the use of sanitary pads, synthetic and/or tight underwear. Makes you feel clean and fresh all day

**Warnings**

- For external use only
- Do not use on damaged or broken skin
- Stop use and ask a Doctor if rash occurs
- Keep out of reach of children

**When using this product**  
Avoid contact with eyes  
**Keep out of reach of children.** In case of overdose get medical help or Contact a Poison Control Center right away.

**Directions**

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

**Other information**

- Keep the product in a cool and dry place

**Inactive Ingredients**  
Aqua, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium PEG-3 Laurylsulfate Sulfosuccinate-Sodium Lauryl Sulfate, Lactic Acid, Diazolidinyl Urea, Glycyrrhizinic Acid, Sodium Benzoate, Potassium Sorbate, Phytosphingosine HCl, Parfum

**Questions or comments ?**  
+34 913456902 Monday to Friday: 9:00 am to 5:00 pm

Lot / Batch:  
Date Fabr. / Mfg. date:  
Date Prérem. / Exp. date:



# GLYZIGEN GEL INTIMATE

glycerin gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-003
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 SULFO SUCCINATE (UNII: D6DH1DTN7E)	3 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
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.01 mg in 1 mL
WATER (UNII: 059QF0K00R)	100 mg in 1 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-003-02	1 in 1 BOTTLE	05/07/2017	
1	NDC:64539-003-01	250 mL in 1 BLISTER 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	05/07/2017	

**Labeler** - Catalysis, SL (862795119)

**Registrant** - Catalysis, SL (862795119)

## Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Catalysis, SL		862795119	manufacture(64539-003)
---------------	--	-----------	------------------------

Revised: 5/2017

Catalysis, SL