

GLIZIGEN SKIN PROTECTANT- glycerin spray
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.

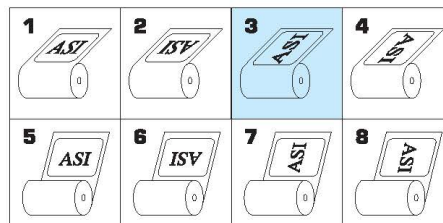
Glycerin 0.5%.....Skin Protectant

Etiqueta_GLIZIGEN_Spray_60ml_Usa_v.1

Tamaño: 77x52 mms
 Colores (Pantones): Cuatricromía,

TOTAL COLORES 4	CUATRICROMIA
	■ CIAN
	■ MAGENTA
	■ AMARILLO
	■ NEGRO

<p>DRUG FACTS</p> <p>Active Ingredients Glycerin 0.5% Purpose: Skin protectant</p> <p>Uses Deodorizes, refreshes and avoids the consequences of the aggressive actions of the detergents on the genital area.</p> <p>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</p> <p>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.</p> <p><small>Lot: / Batch: F. Fab. / Mfg. date: F. Cad. / Exp. date:</small></p>	<p>GLIZIGEN spray Skin protectant</p> <p>60 ml 1.99 fl. oz.</p> 	<p>DRUG FACTS</p> <p>Directions Apply pulverizing over the genital zone, keeping the container in an upright position. 3 or 4 application per day used to be enough, but it can be used as often as necessary.</p> <p>Other information Keep the product in a cool and dry place</p> <p>Inactive Ingredients Propylenglycol, Aqua, Polysorbate 80, Glymizamic Acid, Sodium Benzoate, Potassium Sorbate, TEA.</p> <p>Questions or comments ? +34 913456902 Monday to Friday: 9:00 am to 5:00 pm</p> <p>Catalysis, S.L. Macarena, 14 28016 Madrid / ESPAÑA www.catalysis.es MADE IN SPAIN</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);"> 023-77104 ELIZ Keep out of reach of children. Do not use if plastic in the pump of the bottle is broken or missing </p>
---	---	---	--

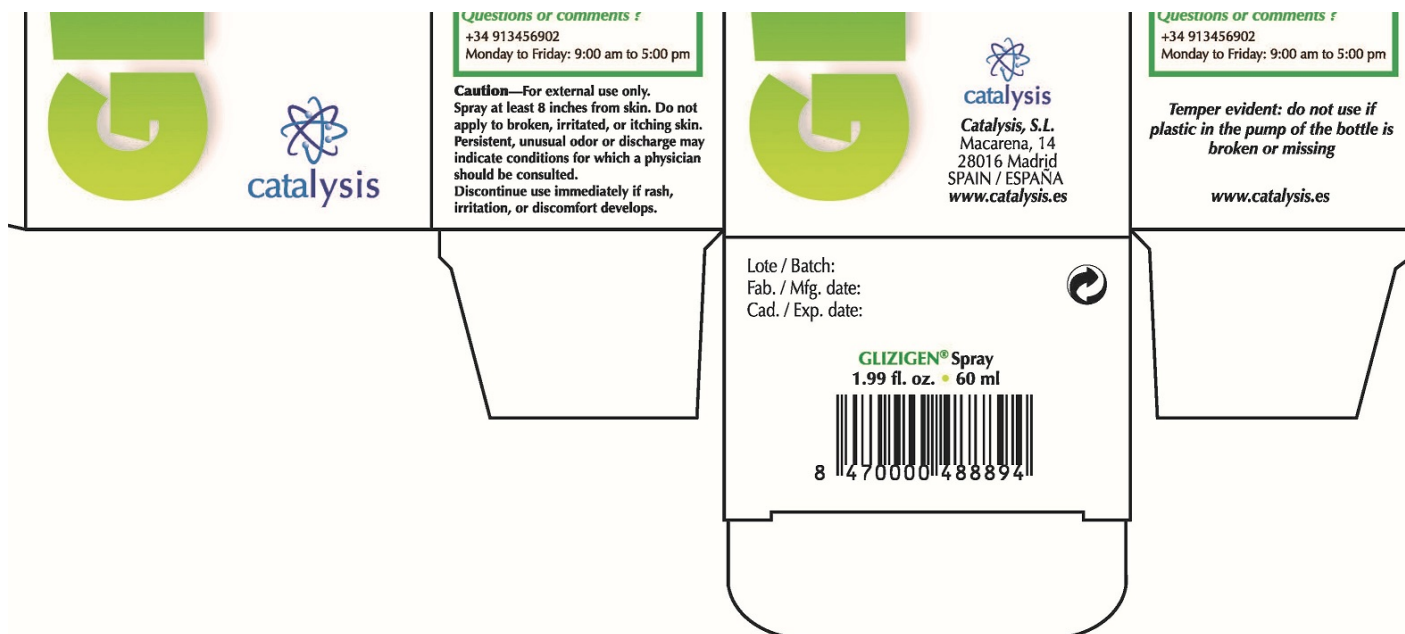


- Stop use and ask a doctor if rash occurs
- Children under 6 months: ask a doctor
- Do not use on damaged or broken skin.
- Keep out of reach of children

- 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
- + 34 913456902 M-F 9:00 am to 5:00 pm
- deodorizes, refreshes and avoids the consequences of the aggressive actions of the detergents in the genital areas
 - apply pulverizing over the genital zone keeping the container in an upright position
 - 3 or 4 applications per day used to be enough, but it can be used as often as necessary
 - apply pulverizing over the genital zone keeping the container in an upright position
 - 3 or 4 applications per day used to be enough, but it can be used as often as necessary

Propyleneglycol, water, Polysorbate 80, Glycyrrhizinic Acid, Sodium Benzoate, Potassium Sorbate, TEA





GLIZIGEN SKIN PROTECTANT

glycerin spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-018
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
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.8 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 mg in 1 mL
WATER (UNII: 059QF0KO0R)	100 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	50 mg in 1 mL
TEA LEAF (UNII: GH42T47V24)	0.1 mg in 1 mL
GLYCYRRHIZIN (UNII: 6FO62043WK)	0.1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-018-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/22/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/22/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment			
Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-018)

Revised: 3/2018

Catalysis, SL