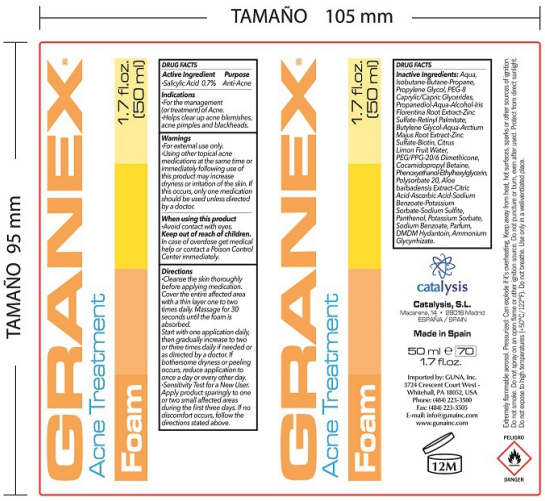
GRANEX FOAM ACNE TREATMENT- salicylic acid aerosol, foam
Catalysis, SL

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.

Granex Foam Acne Treatment

Salicylic Acid 0.7%.....Anti Acne

Tubo Granex espuma 50ml USA V.3



- 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.

- For external use only
  - Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor

- Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to two times daily. Massage for 30 seconds until the foam is absorbed Because excessive drying of the skin may occur. start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day

- "Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above

For the management (or treatment) of Acne
Helps clear up acne blemishes, acne pimples, blackheads

+ 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

Aqua, Isobutane, Butane, Propane, Propylene Glycol, PEG-8 Caprylic/Capric Glycerides, Propanediol, Aqua, Alcohol, Iris Florentina Root Extract, Zinc Sulfate, Retinyl Palmitate, Butylene Glycol, Aqua, Arctium Majus Root Extract, Zinc Sulfate, Biotin, Citrus Limon Fruit Water, PEG/PPG-20/6 Dimethicone, Cocamidopropyl Betaine, Phenoxyethanol, Ethylhexylglycerin, Polysorbate 20, Aloe barbadensis Extract, Citric Acid, Ascorbic Acid, Sodium Benzoate, Potassium Sorbate, Sodium Sulfite , Panthenol, Potassium Sorbate, Sodium Benzoate, Parfum, Glycyrrhizic Acid

Granex Foam Anti Acne Treatment

Caja Granex espuma 50ml USA V.5

GRANEX FOAM ACNE TREATMENT

salicylic acid aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64539-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	2.25 mg in 1 mL
BIOTIN (UNII: 6SO6U10H04)	2.25 mg in 1 mL
PEG/PPG-20/6 DIMETHICONE (UNII: PWZ7N4UIKE)	1.8 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.9 mg in 1 mL
ALOE (UNII: V5VD430YW9)	0.45 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.45 mg in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.45 mg in 1 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.45 mg in 1 mL
GLYCYRRHIZIN (UNII: 6FO62043WK)	0.09 mg in 1 mL
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	1.35 mg in 1 mL
ISOBUTANE (UNII: BXR49TP611)	6 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.45 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	2.25 mg in 1 mL
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	2.25 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M)	2.25 mg in 1 mL
IRIS X GERMANICA NOTHOVAR. FLORENTINA ROOT (UNII: M30XO5X4XD)	2.25 mg in 1 mL
ZINC SULFATE (UNII: 89DS0H96TB)	2.25 mg in 1 mL
WATER (UNII: 059QF0KO0R)	2.25 mg in 1 mL
ARCTIUM MINUS ROOT (UNII: IS8QAQ61Q5)	2.25 mg in 1 mL
CITRUS X LIMON FRUIT OIL (UNII: 0HNC1J1YED)	2.25 mg in 1 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.54 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.45 mg in 1 mL
SODIUM SULFITE (UNII: VTK01UQK3G)	0.45 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-008-02	1 in 1 BOX	01/11/2018	
1	NDC:64539-008-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/11/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-008)

Revised: 1/2018 Catalysis, SL