BREXTEM S- niacinamide liquid Brexogen Inc.

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.

Active ingredient(s)

Niacinamide 2.0%

Purpose

Skin Brightening

Use(s)

■ Helps brighten skin tone.

Warnings

For external use only

- 1.Discontinue use if signs of irritation or rashes appear. If symptoms get worse, consult with a dermatologist. 1) In case of swelling, itching, or other side effects while or after using this product.
- 2. Do not apply to open wounds.
- 3. Avoid contact with eyes.
- 4. Precautions for storage and handling.
- 5. Keep in the refrigerator at 2-6°C.
- 6. Keep out of reach of children
- 7. Avoid direct sunlight

KEEP OUT OF REACH OF CHILDREN

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Directions

■ Gently mix with BREXTEM powder to dissolve the mixture. Take proper amount and gently apply onto the skin.

Questions

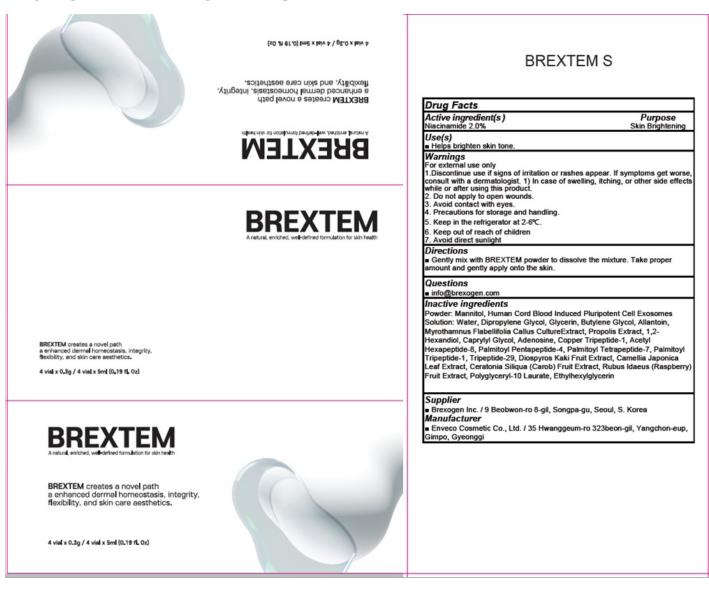
■ info@brexogen.com

Inactive ingredients

Powder: Mannitol, Human Cord Blood Induced Pluripotent Cell Exosomes

Solution: Water, Dipropylene Glycol, Glycerin, Butylene Glycol, Allantoin, Myrothamnus Flabellifolia Callus CultureExtract, Propolis Extract, 1,2-Hexandiol, Caprylyl Glycol, Adenosine, Copper Tripeptide-1, Acetyl Hexapeptide-8, Palmitoyl Pentapeptide-4, Palmitoyl Tetrapeptide-7, Palmitoyl Tripeptide-1, Tripeptide-29, Diospyros Kaki Fruit Extract, Camellia Japonica Leaf Extract, Ceratonia Siliqua (Carob) Fruit Extract, Rubus Idaeus (Raspberry) Fruit Extract, Polyglyceryl-10 Laurate, Ethylhexylglycerin

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



BREXTEM S

niacinamide liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83630-010	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Niacinamide (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	Niacinamide	2.0 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Dipropylene Glycol (UNII: E107L85C40)			
Glycerin (UNII: PDC6A3C0OX)			
Butylene Glycol (UNII: 3XUS85K0RA)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:83630-010- 02	4 in 1 BOX	08/01/2023		
1	NDC:83630-010- 01	5 mL in 1 VIAL; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2023	

Labeler - Brexogen Inc. (695721823)

Registrant - Brexogen Inc. (695721823)

Establishment					
Name	Address	ID/FEI	Business Operations		
Enveco Cosmetic Co., Ltd.		689061861	manufacture(83630-010)		

Revised: 9/2023 Brexogen Inc.