

**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**

KEEP OUT OF REACH OF CHILDREN

**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 Culture Extract, 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



4 vial x 0.3g / 4 vial x 5ml (0.19 fl. Oz)

BREXTEM creates a novel path  
a enhanced dermal homeostasis, integrity,  
flexibility, and skin care aesthetics.

**BREXTEM**  
A natural, enriched, well-defined formulation for skin health

---

**BREXTEM**  
A natural, enriched, well-defined formulation for skin health

BREXTEM creates a novel path  
a enhanced dermal homeostasis, integrity,  
flexibility, and skin care aesthetics.

4 vial x 0.3g / 4 vial x 5ml (0.19 fl. Oz)

BREXTEM S

Drug Facts	Purpose
<b>Active ingredient(s)</b> Niacinamide 2.0%	Skin Brightening
<b>Use(s)</b> ■ Helps brighten skin tone.	
<b>Warnings</b> 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	
<b>Directions</b> ■ Gently mix with BREXTEM powder to dissolve the mixture. Take proper amount and gently apply onto the skin.	
<b>Questions</b> ■ info@brexogen.com	
<b>Inactive ingredients</b> Powder: Mannitol, Human Cord Blood Induced Pluripotent Cell Exosomes Solution: Water, Dipropylene Glycol, Glycerin, Butylene Glycol, Allantoin, Myrothamnus Flabellifolia Callus Culture Extract, 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	
<b>Supplier</b> ■ Brexogen Inc. / 9 Beobwon-ro 8-gil, Songpa-gu, Seoul, S. Korea	
<b>Manufacturer</b> ■ Enveco Cosmetic Co., Ltd. / 35 Hwanggeum-ro 323beon-gil, Yangchon-eup, Gimpo, Gyeonggi	

## BREXTEM S

niacinamide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83630-010
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Niacinamide</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	Niacinamide	2.0 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Dipropylene Glycol</b> (UNII: E107L85C40)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	

**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.