

**LE PHOQUA HAIR REGROWTH SERUM BIOTIN 5% MINOXIDIL- hair regrowth serum liquid  
Stellans Inc.**

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**Active Ingredient**

Minoxidil 5% w/v.....Hair Regrowth Treatment

**Purpose**

Hair Regrowth Treatment

**Use**

Use to regrow hair on the top of the scalp (vertex only, see pictures on side of carton)

**Warnings**

- For external use only.
- Flammable: Keep away from fire or flame.

**Do not use**

- You are a woman. Your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. Minoxidil topical solution 5% is not intended for frontal baldness or receding hairline.
- You have no family history of hair loss
- Your hair loss is sudden and/or patchy
- You do not know the reason for your hair loss
- You are under 18 years of age.
- Your scalp is red.

**Stop Use**

- Chest pain, rapid heartbeat, faintness , or dizziness occurs
- sudden, unexplained weight gain occurs
- Your hands or feet swell scalp irritation or redness occurs
- Unwanted fa cial hair growth occurs
- You do not see hair regrowth in 4 months
- May be harmful if used when pregnant or breast-feeding.
- Keep out of reach of children,
- If swallowed, get medical help or contact a Poison Control Center right away.

**Keep Oot Of Reach Of Children**

Do not place this product within the reach of children

## **Directions**

1. Apply 1 ml with dropper 2 times a day directly onto the scalp in the hair loss area.
  2. Using more or more often will not improve results continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again.
- check grammar

## **Other information**

\*Before use, read all information on carton and enclosed leaflet

\*Keep the carton. It contains important information.

hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with minoxidil topical solution 5% for men

\*In clinical studies with mostly white men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%

\*Store at 20° to 25°C (68° to 77°F). Keep tightly closed.

## **Inactive ingredients**

Alcohol

Propylene Glycol

Purified Water

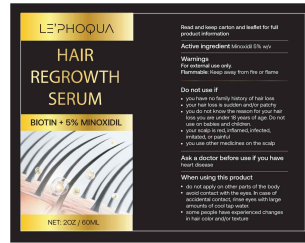
## **Questions**

CONTACT US

[www.lephoqua.com](http://www.lephoqua.com)

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## **PRINCIPAL DISPLAY PANEL**



72 x 94 mm

# LE PHOQUA HAIR REGROWTH SERUM BIOTIN 5% MINOXIDIL

hair regrowth serum liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83565-007
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83565-007-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/24/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075357	11/24/2023	

**Labeler** - Stellans Inc. (111157321)

## Establishment

Name	Address	ID/FEI	Business Operations
Stellans Inc.		111157321	label(83565-007) , manufacture(83565-007)

Revised: 11/2023

Stellans Inc.