



HU000034582T2

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Szellemi Tulajdon Nemzeti Hivatala**EURÓPAI SZABADALOM**  
**SZÖVEGÉNEK FORDÍTÁSA**(21) Magyar ügyszám: **E 06 774072**  
(22) A bejelentés napja: **2006. 06. 26.**(51) Int. Cl.: **A61K 8/67** (2006.01)  
**A61Q 7/00** (2006.01)(96) Az európai bejelentés bejelentési száma:  
**EP 20060774072**(86) A nemzetközi (PCT) bejelentési szám:  
**PCT/US 06/024921**(97) Az európai bejelentés közzétételi adatai:  
**EP 1898867 A1** **2007. 01. 04.**(87) A nemzetközi közzétételi szám:  
**WO 07002640**(97) Az európai szabadalom megadásának meghirdetési adatai:  
**EP 1898867 B1** **2017. 08. 09.**

(30) Elsőbbségi adatok: <b>693716 P</b> <b>2005. 06. 24.</b> <b>US</b>
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(54) **Eljárás hajnövekedési rendellenességek, így például női alopecia kezelésére, és ehhez használható készítmények**

Az európai szabadalom ellen, megadásának az Európai Szabadalmi Közlönyben való meghirdetésétől számított kilenc hónapon belül, felszólalást lehet benyújtani az Európai Szabadalmi Hivatalnál. (Európai Szabadalmi Egyezmény 99. cikk(1))

A fordítást a szabadalmat az 1995. évi XXXIII. törvény 84/H. §-a szerint nyújtotta be. A fordítás tartalmi helyességét a Szellemi Tulajdon Nemzeti Hivatala nem vizsgálta.

(19)



(11)

**EP 1 898 867 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:  
**09.08.2017 Bulletin 2017/32**

(51) Int Cl.:  
**A61K 8/67 (2006.01) A61Q 7/00 (2006.01)**

(21) Application number: **06774072.0**

(86) International application number:  
**PCT/US2006/024921**

(22) Date of filing: **26.06.2006**

(87) International publication number:  
**WO 2007/002640 (04.01.2007 Gazette 2007/01)**

(54) **METHOD FOR TREATING HAIR GROWTH DISORDERS, SUCH AS FEMALE PATTERN ALOPECIA, AND COMPOSITIONS USEFUL THEREFORE**

VERFAHREN ZUR BEHANDLUNG VON HAARWACHSTUMS-STÖRUNGEN, WIE Z.B. WEIBLICHE ALOPEZIE UND NÜTZLICHE ZUSAMMENSETZUNGEN DAFÜR

MÉTHODE DE TRAITEMENT DE TROUBLES DE LA CROISSANCE DES CHEVEUX, TELS QUE L ALOPÉCIE FÉMININE, ET PRÉPARATIONS EMPLOYÉES DANS LE CADRE DESDITES MÉTHODES

(84) Designated Contracting States:  
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR**

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(30) Priority: **24.06.2005 US 693716 P**

(43) Date of publication of application:  
**19.03.2008 Bulletin 2008/12**

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**Description****RELATED APPLICATION**

5 [0001] This application claims priority of Serial No. 60/693,716, filed June 24, 2005.

**FIELD OF THE INVENTION**

10 [0002] This invention relates to methods for treating disorders such as hair loss, pattern hair loss (alopecia), in particular. It also relates to increasing the content of NAD in hair follicles, thus increasing the energy available in these tissues, which in turn leads to enhanced growth, fullness, thickness, and overall quality of scalp hair. Even more particularly, the invention relates to treatment of these conditions in females.

**BACKGROUND AND PRIOR ART**

15 [0003] Female pattern hair loss (alopecia) affects approximately 20 million women. Hair loss begins at puberty and progresses throughout life. Early detection of the condition is difficult, which is unfortunate, since early diagnosis and treatment are important in achieving optimal therapy. While the pattern of hair loss varies considerably, a decreased hair count over the entire top of the scalp commonly occurs. A good indicator of female pattern hair loss is a widening part line or a thinning ponytail. Typically, daily hair loss counts do not exceed 100-125 hairs; however hair follicles that enter the telogen phase do not reenter the anagen growth phase, resulting in a slow net loss of active follicles. The treatment options for this condition are limited and include hair transplants, hormonal supplementation and minoxidil, a drug that affects calcium homeostasis. See, Li, et al., J Invest Dermatol 117(6): 1594-1600 (2001). Topical 2% and minoxidil, the only approved drug therapies for this condition.

20 [0004] The limited treatment options available for female alopecia has led to the search for other agents that can provide benefit for this condition. A potential candidate for hair growth promotion is niacin (nicotinic acid). Studies have identified several possible mechanisms suggesting that nicotinic acid may benefit these conditions. The major bioactive form of niacin, nicotinamide adenine dinucleotide (NAD) plays a central role in cellular energy metabolism and, the hair follicle has high energy requirements (Jacobson, et al., J Photochem Photobiol B 63(1-3):141-7 (2001)). NAD is also the substrate for enzymes involved in the maintenance of genomic integrity (Jacobson, et al., Trends Biochem Sci, 24(11):415-417 (1999)) and calcium homeostasis (Lee, Curr. Mol. Med., 4(3):227-237 (2004)). Additionally, skin has been shown to contain niacin receptors that stimulate leptin release (Kim, et al., J. Invest. Dermatol., 119:347 (2002)) and downstream regulators in the leptin pathway are involved in skin homeostasis (Komuves, et al., J Invest Dermatol, 115(3):361-367 (2000)) and hair follicle cycling (Sano, et al., EMBO J., 18(17):4657-4668 (1999)). While either niacin or its other vitamin form, niacinamide, have the potential to be converted to NAD, the nicotinic acid receptor responds only to niacin (Tunaru, et al., Nat. Med., 9(3):352-355 (2003)).

25 [0005] While niacin has the potential to provide benefit to skin and scalp, delivery of niacin *per se* is not feasible in appreciable amounts, as it causes intense vasodilation at the site of application and its physical properties do not allow it to achieve a prolonged residence time in the skin. This has led to the development of myristyl nicotinate, a niacin derivative that effects delivery to skin cells without vasodilation and creates a residence time allowing conversion to NAD (Jacobson, et al., J. Invest. Dermatol., 114:849 (2000), and U.S. Patent No. 6,337,065 and stimulation of the nicotinic acid receptor. (Tunaru, et al., *supra*). Myristyl nicotinate has been shown to promote epidermal differentiation leading to strong enhancement of skin barrier integrity (Jacobson, et al., in Alberts, et al., ed. Fundamentals of Cancer Prevention (Springer, 2005, pgs. 139-160). Another niacin derivative, octyl nicotinate, stimulates blood flow and oxygen delivery to tissue. See, e.g., U.S. Patent No. 6,924,299. The '299 patent, however, is silent as to the use of the described compounds in the context of hair growth or, treatment of disorders of hair growth, or any related conditions.

30 [0006] A feature of the invention thus relates to methods as defined in claims 6-8 via the administration of nicotinic acid alkyl esters. In some cases, administration of mixtures of two or more nicotinic acid alkyl esters in a composition or formulation, will be desired.

35 [0007] When two or more of these nicotinic acid alkyl esters are used in composition form, such compositions are also a feature of this invention.

[0008] Further features of the invention and its operation will be clear from the discussion which follows.

**SUMMARY OF THE INVENTION**

40 [0009] The invention relates to compositions which are useful in the stimulation of hair follicles, with a resulting benefit of treating hair growth disorders, such as alopecia, in females in particular. Methods of treatment of relevant populations are also a feature of the invention.

[0010] The compositions, in their broadest aspect, are defined in appended claim 1. The first nicotinic acid alkyl ester is myristyl nicotinate which delivers niacin to cells, hair follicle cells in particular, without vasodilation, wherein the nicotinic acid alkyl ester has sufficient residence time to be converted to niacin without the adverse effect of vasodilation.

[0011] The second nicotinic acid alkyl ester is octyl nicotinate which stimulates blood flow, and hence oxygen delivery to the cells.

[0012] The first nicotinic acid alkyl ester is one where the alkyl moiety is C14 alkyl ester. The second nicotinic acid alkyl ester is one where the alkyl group is shorter than that in the first compound, and is a C8 alkyl ester.

[0013] The composition comprises a C14 nicotinic acid alkylester, and a C8 nicotinic acid alkyl ester. Optionally, ingredients such as those set forth in U.S. Patent No. 6,337,065, U.S. Patent No. 6,464,942, and/or U.S. Patent No. 6,924,299 may be included in the composition.

[0014] Either of the first and second nicotinic acid alkyl esters, as described supra, are combined in a composition as described supra.

## BRIEF DESCRIPTION OF THE FIGURES

[0015]

Figures 1A and 1B are "before and after" photos which show the impact of the formulations of the invention on hair growth.

Figure 2 shows the data of Table 2, in graphic form.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

### EXAMPLE 1

[0016] Sixty female subjects, ages 20-80, who completed an informed consent procedure with Ludwig type I-III female pattern hair loss (Ludwig, et al., Br. J. Dermatol., 97(3):247-254 (1977)) were enrolled in a 6-month pilot study using a double blinded, placebo controlled design. Subjects were assigned randomly to the placebo (20, vehicle only) or active groups (40, vehicle containing 0.5% octyl nicotinate and 5.0% myristyl nicotinate). Dispensed products were packaged in identical containers. Trisiloxane and dimethicone were major components of the formulation. Since the actives are vitamin-derived substances, both the placebo and the active preparations studied are classified as cosmetics under the current FDA guidelines.

[0017] At baseline, subjects were dispensed a one month supply of assigned study product. The first dose was applied at the research center by a study nurse. Subjects were instructed to apply the formula, at night, in 6 metered doses to the scalp in the following manner: one drop each to the right anterior scalp, left anterior scalp, right middle top of the head, left middle top of the head, right posterior scalp, and left posterior scalp. If the hair was washed, the study medication was applied following hair washing. All subjects were supplied with the same shampoo. The frequency of hair washing was self selected. Subjects were asked to maintain the entry style, color, and curl of their hair throughout the study.

[0018] Subjects returned at monthly intervals for evaluation of increased hair fullness, scalp irritation, or other adverse events and product dispensing. They were asked to shampoo the morning of study visit and to avoid applying styling products. Subjects were also asked to assess the appearance of their hair. Standardized photography was used for the assessment of hair fullness since increases in hair fullness over the 6-month study period are normally not detectable by either the investigator or the subjects. At baseline, month 3, and month 6, photos of the scalp vertex, with the hair combed away from the vertex like the spokes of the wheel, and the central partline, with the hair combed smoothly to both sides of the head. These images were taken in duplicate with one set provided to the subjects for personal comparison while the second set remained at the study center. Standardized 35 mm photography was conducted at baseline, 2, 4, and 6 months as follows: vertex view with hair combed away from the crown, superior view with hair parted in midline, frontal view with headband to reveal the anterior hairline. The images were taken with the subject's head in a 3-point mount specially designed for hair loss photography. Evaluation was completed on the 6 month photographs as this represents a minimal time to detect changes in hair fullness.

[0019] Of the total subjects enrolled in the study, 32 of 40 active and 12 of 20 placebo subjects completed the study. A relatively high withdrawal rate is typical for hair fullness/growth studies but it is interesting to note that proportionally twice as many subjects in the placebo group withdrew from the study. Overall tolerability of the topical formulations was very good. There were no serious adverse events reported and the mild adverse events included 9 reports of scalp stinging, 2 of scalp burning, 12 of scalp itching, 4 reports of scalp redness, and 7 reports of eye irritation. These events occurred in both placebo and active groups indicating that the volatile vehicle and not the active ingredients was the source of the irritation.

[0020] The study yielded investigator assessments, subject assessments, and photographic assessments. Statistical Polaroid photos and subject assessments revealed a positive trend, but did not reach significance at a p value of 0.05, which was not unexpected for a 6-month study. The key assessment was based on the standardized 35 mm photographs that were evaluated by a blinded investigator for assessment of improvement in hair fullness. Each set of images was rated on a scale of minus 1 for decreased hair fullness, zero for no change, or plus 1 for increased hair fullness. These data are summarized in Table 1. The data comparing the placebo and active groups demonstrate an increased benefit for the active group with a p value of 0.04 as analyzed by the one tailed Mann Whitney test for nonparametric data. The placebo effect observed in this study is not uncommon for hair fullness studies. An example of the effect of nicotinic acid derivatives on thinning hair as documented by 35 mm photography at baseline and 6 months of application is shown in Figure 1.

Table 1

Evaluation of nicotinic acid derivatives on female pattern alopecia					
Group	No of subjects	Scoring of hair growth number of subjects (% of total)			p value <sup>#</sup>
		Decrease	No change	Increase	
Placebo	20* (12 <sup>‡</sup> )	1 (8%)	7 (59%)	4 (33%)	---
Active <sup>¶</sup>	40* (32 <sup>‡</sup> )	2 (6%)	8 (25%)	22 (69%)	0.04

\* number of subjects enrolled in study  
<sup>‡</sup> number of subjects who completed the study  
<sup>#</sup> active compared to placebo for one tailed Mann Whitney test  
<sup>¶</sup> active contained 0.5% octyl nicotinate and 5.0% myristyl nicotinate

EXAMPLE 2

[0021] This example describes how application of the nicotinic acid alkyl esters of the invention improved the energy status of hair follicles, by increasing NAD content therein.

[0022] Hair samples were taken from subjects treated with the formulation of Example 1, and tested for NAD content, as well as DNA content, using art recognized methods. The results follow, in Table 2, and Figure 2.

Table 2

Subject	NAD-DNA pmol/ng Baseline	NAD/DNA pmol/ng 7 Days	Change	% Change
1	0.136	0.194	0.058	43
2	0.104	0.157	0.053	51
3	0.080	0.137	0.057	71
4	0.107	0.132	0.025	23
5	0.062	0.085	0.023	37
6	0.069	0.072	0.004	51
7	0.079	0.103	0.025	31
<b>Mean</b>	<b>0.091</b>	<b>0.126</b>	<b>0.035</b>	<b>37</b>
<b>p=</b>			<b>0.005</b>	

[0023] These results show clearly that the nicotinic acid alkyl esters of the invention increase the amount of NAD in hair follicles. Expressed another way, the energy content of the follicles increased, and the increases, as can be seen, are quite dramatic.

[0024] The foregoing disclosure sets forth various features of the invention, which relates to compositions useful in treating hair growth disorders, such as pattern baldness, and the use of these compositions. The compositions comprise a first nicotinic acid alkyl ester, which is the nicotinic acid alkyl ester where the alkyl group contains 14 CH<sub>2</sub> groups, i.e.,

myristyl nicotinate.

[0025] The second nicotinic acid alkyl ester is the straight chain nicotinic acid alkyl ester octyl nicotinate.

[0026] The two nicotinic acid alkyl esters are combined in a formulation, optionally with a carrier, which may be water, a soap, a detergent, or any other standard carrier useful for application to the scalp.

5 [0027] The formulations of the invention may be in any form that is suitable for administering materials to the scalp. Exemplary, but by no means exclusive examples of such forms are topical solutions shampoos, rinses, aerosols, emulsions, crèmes, sprays, lotions, gels, and so forth.

[0028] The compositions are used by applying them to the scalp, such as by washing, massaging, and so forth. It is preferred that the formulations be applied at least once a day, preferably at a dose of from about .01% to about 10%, w/v for each of the components, more preferably from about .1% to about 5% w/v for each component per day. Different dosing regimens may also be used.

[0029] As was shown, supra, these nicotinic acid alkyl esters cause an increase in intrafollicular NAD<sup>+</sup> content, as manifested in an increased NAD<sup>+</sup>/DNA ratio, in the hair follicles. Thus, in turn, results in an increase in intrafollicular energy content, which may be the reason for the alleviation of the hair loss.

15 [0030] Nicotinic acid alkyl esters may be so used, with the C8 and C14 alkyl chains.

[0031] Also a part of the invention is a method for increasing thickness or fullness of pre-existing hair as defined in claim 6. It has been observed, as these data show, that the use of these formulations, in addition to alleviating hair loss, results in an increase in hair fullness and/or thickness.

[0032] Other aspects of the invention will be clear to the skilled artisan, and need not be reiterated here.

20

### Claims

1. A composition useful in treating a hair loss disorder comprising:

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- (i) a first nicotinic acid alkyl ester which is myristyl nicotinate,
- (ii) a second nicotinic acid alkyl ester which is octyl nicotinate and
- (iii) a pharmaceutically acceptable carrier.

30 2. The composition of claim 1, in the form of a topical solution shampoo, rinse, aerosol, emulsion, lotion, creme, or gel.

3. A composition according to claim 1 or 2 for use in the treatment of a hair loss disorder in a subject.

4. A composition for use according to claim 3 wherein the subject is a female.

35

5. A composition for use according to claim 3 or 4, wherein said subject suffers from alopecia.

6. A method for increasing thickness or fullness of pre-existing hair, comprising applying to the scalp of a subject in need thereof an amount of the composition set forth in claim 1 to hair on the scalp of a subject in need thereof, in an amount sufficient to increase thickness or fullness of pre-existing hair.

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7. A method according to claim 6 wherein the subject is a female.

8. A composition for use according to claim 3 and for increasing thickness or fullness of pre-existing hair wherein the subject is a female which suffers from alopecia.

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### Patentansprüche

1. Zusammensetzung geeignet zur Behandlung von Haarausfallstörung aufweisend:

50

- i) einen ersten Nikotinsäure-Akylester, welcher ein Myristylnicotinat ist,
- ii) ein zweiter Nikotinsäure-Akylester, welcher ein Octylnicotinat ist und
- iii) ein pharmazeutisch akzeptierbarer Träger.

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2. Zusammensetzung nach Anspruch 1, in Form einer topischen Lösung, Shampoo, Spülung, Aerosol, Emulsion, Lotion, Creme oder Gel.

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3. Zusammensetzung nach Anspruch 1 oder 2 zur Verwendung bei der Behandlung von Haarausfallstörungen bei einem Subjekt.
- 5 4. Zusammensetzung zur Verwendung nach Anspruch 3, wobei das Subjekt eine Frau ist.
5. Zusammensetzung zur Verwendung nach Anspruch 3 oder 4, wobei das Subjekt an Haarausfall leidet.
6. Verfahren zum Erhöhen der Dicke oder der Fülle von bereits existierendem Haar, aufweisend das Aufbringen auf die Kopfhaut eines Subjekts, in einer Menge gemäß Bedarf der Zusammensetzung gemäß Anspruch 1 auf das Haar auf der Kopfhaut eines Subjekts gemäß dessen Bedarf in einer Menge ausreichend zum Verbessern der Dicke oder der Fülle von bereits existierendem Haar.
- 10 7. Verfahren gemäß Anspruch 6, wobei das Subjekt eine Frau ist.
- 15 8. Zusammensetzung zur Verwendung gemäß Anspruch 3 und zum Verbessern der Dicke oder der Fülligkeit von bereits existierendem Haar, wobei das Subjekt eine Frau ist, welche unter Haarausfall leidet.

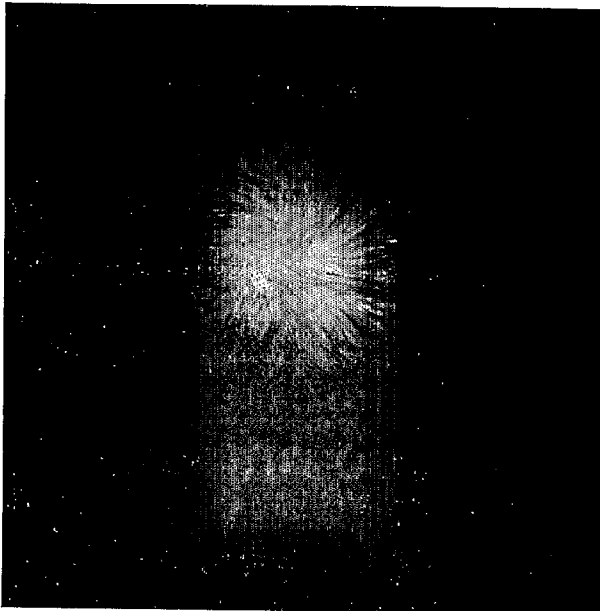
### Revendications

- 20 1. Composition utile dans le traitement d'un trouble de perte des cheveux comprenant :
  - (i) un premier alkyl ester d'acide nicotinique qui est le nicotinate de myristyle,
  - (ii) un second alkyl ester d'acide nicotinique qui est le nicotinate d'octyle et
  - 25 (iii) un support pharmaceutiquement acceptable.
2. Composition selon la revendication 1, sous la forme d'un shampoing, d'un produit de rinçage, d'un aérosol, d'une émulsion, d'une lotion, d'une crème, ou d'un gel de solution topique.
- 30 3. Composition selon la revendication 1 ou 2, pour une utilisation dans le traitement d'un trouble de perte des cheveux chez un sujet.
4. Composition pour une utilisation selon la revendication 3, dans laquelle le sujet est une femme.
- 35 5. Composition pour une utilisation selon la revendication 3 ou 4, dans laquelle ledit sujet souffre d'alopecie.
6. Procédé pour augmenter l'épaisseur ou le volume des cheveux pré-existants comprenant l'application au cuir chevelu d'un sujet qui en a besoin, d'une quantité de la composition exposée dans la revendication 1 aux cheveux sur le cuir chevelu d'un sujet qui en a besoin, dans une quantité suffisante pour augmenter l'épaisseur ou le volume des cheveux pré-existants.
- 40 7. Procédé selon la revendication 6, dans lequel le sujet est une femme.
- 45 8. Composition pour une utilisation selon la revendication 3 et pour augmenter l'épaisseur ou le volume des cheveux pré-existants, dans laquelle le sujet est une femme qui souffre d'alopecie.

50

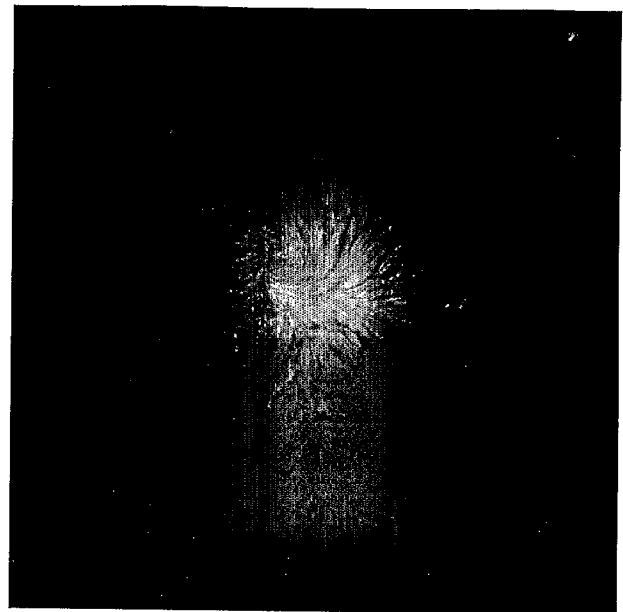
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**Figure 1:** An example of the effect of nicotinic acid derivatives on thinning hair as documented by 35 mm photography at baseline and 6 months of application.



Baseline

A



6 months

B

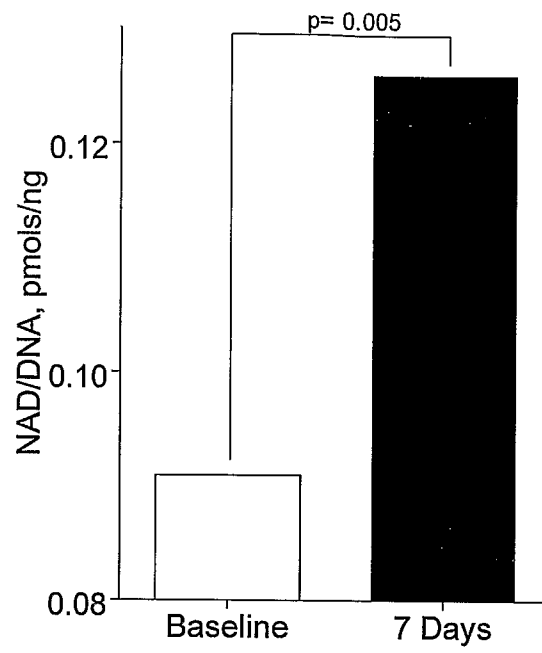


Figure: Effect of lipophilic derivatives of niacin on hair follicle NAD

**FIGURE 2**

**REFERENCES CITED IN THE DESCRIPTION**

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## ELJÁRÁS HAJNÖVEKEDÉSI RENDELLENESÉGEK, ÍGY PÉLDÁUL NŐI ALOPECIA KEZELÉSÉRE, ÉS EHHEZ HASZNÁLHATÓ KÉSZÍTMÉNYEK

### Szabadalmi igénypontok:

1. Készítmény, amely használható hajhullásos rendellenesség kezelésében, és tartalmaz:

- (i) egy első nikotinsav-alkilésztert, amely mirisztil-nikotinát,
- (ii) egy második nikotinsav-alkil-észtert, amely oktil-nikotinát és
- (iii) gyógyászatilag elfogadható hordozóanyagot.

2. Az 1. igénypont szerinti készítmény helyileg alkalmazható oldat, sampon, öblítő, aeroszol, emulzió, lotion, krém vagy gél formában.

3. Az 1. vagy 2. igénypont szerinti készítmény egy alany hajhullásos rendellenességének kezelésében való alkalmazásra.

4. Készítmény alkalmazásra a 3. igénypont szerint, ahol az alany nő.

5. Készítmény alkalmazásra a 3. vagy 4. igénypont szerint, ahol az említett alany alopeciában szenved.

6. Eljárás már meglévő haj dúságának vagy teltségének növelésére, amelynek során felvisszük az 1. igénypont szerinti készítmény olyan mennyiségét a kezelésre szoruló alany fejbőrére vagy a kezelésre szoruló alany fejbőrén levő hajára, amely elegendő a már meglévő haj dúságának vagy teltségének a növelésére.

7. A 6. igénypont szerinti eljárás, ahol az alany nő.



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8. Készítmény alkalmazásra a 3. igénypont szerint és már meglévő haj dúságának vagy teltségének növelésére, ahol az alany alopeciában szenvedő nő.