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THE USE OF L-LYSINE IN THE TREATMENT OF HAIR LOSS

The use of L-lysine in the manufacture of a medicament for the prophylaxis and treatment of hair loss in humans, particularly telogen effluvium, is provided. A kit is also provided which includes a plurality of separate containers, each containing at least one active agent useful in a combination therapy for the treatment of genetic hair loss, wherein said kit includes L-lysine and at least further active agent selected from minoxidil, anti-androgens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.
The Use of L-Lysine in the Treatment of Hair Loss

The present invention provides a medicament for the prophylaxis and treatment of hair loss, particularly telogen effluvium, in humans. It further provides a kit useful in a combination therapy for the treatment of genetic hair loss.

Scalp hair loss can be divided into the following three main groups and any one group or combinations of said groups may be operating in an individual at any point in time:

1. Hair loss caused by a reduction in the number of hairs per unit area (cm²);
2. Hair loss caused by a reduction in the diameter of hair; and
3. Hair loss caused by an increase in the number of hairs in the telogen (resting) phase, or an increase in the length of time (latency period) between the end of the telogen phase and the initiation of the next anagen (growing) phase.

It is normal to lose some scalp hair each day. There are natural fluctuations in the hair cycle which in turn influence the amount of hair shed from the scalp on a daily basis. It is therefore important to establish if a problem involving excessive hair shedding really exists and that the individual has not just become aware of their normal daily loss.

For most humans, scalp hair has a life cycle of between 1000 and 2000 days (2 ¾ and 5½ years), following which there is a short period of rest (the telogen phase), which lasts approximately one hundred days. For the majority of its life cycle, scalp hair is in a growth phase known as the anagen phase. As the new hair grows up the follicle it loosens the old resting hair (telogen hair) which is usually dislodged with brushing, combing or shampooing.
This cycle continues unless the hair metabolism is disturbed. Since shed hair is almost entirely telogen hair, the loss from the scalp is seen 10 to 12 weeks later.

For normal individuals having 100,000 hairs, the above process results in about 100 hairs per day being lost from the scalp, while for individuals with 150,000 hairs around 150 per day are lost. These figures are for a 1000 day cycle. For a 2000 day cycle, these values would be halved. Scalp hair grows around 0.33 mm per day and with a growth cycle of 1000 days the hair would grow to a length of 33 cm and for 2000 days 66 cm.

Most transient and temporary effects on the hair cycle, which also cause increased hair shedding, correct themselves and no further action is required. Sometimes it is difficult to determine if the natural rate of hair shedding has increased or excessive shedding has declined, since an individual may be unaware of their normal rate. However if a true problem exists, such as occurs in a nutritional imbalance, the consequences can be detected as a reduction in hair volume. This is because the prolonged effect upon the hair cycle causes significant change to the overall amount of hair present.

Many women are aware of an increase in the amount of hair shed daily which will be seen as more hair in the brush, comb, on the bathroom floor, or when they shampoo. When there is no obvious cause (e.g. an illness within the past three months, taking medication known to produce hair loss, or pregnancy), then it is important to consider suboptimal hair growth where increased hair shedding is the primary feature.

The problem of increased hair shedding (telogen effluvium) and suboptimal hair growth principally affects women in the menstrual years and may co-exist with other hair loss disturbances either of a hormonal or nutritional basis. The loss of hair in this condition is the result of an increase in the amount of telogen hair shed from the scalp. It may also involve a reduction in the length of hair grown.

Increased scalp hair shedding results from an excessive amount of telogen hair. Increased hair shedding of this type is usually identified by measuring the ratio of hair in the anagen and telogen phases. In the chronic state there may be no perceived increase in
shedding because of a plateau effect in the anagen/telogen ratio, but its consequence is an increase in the number of hairs unable to grow to a given length. Frequently, female sufferers complain of a reduction in the amount of hair they can pin, clip or tie-up, compared to previously. The variable measured to identify this aspect is usually the amount of hair less than 30 mm in length.

Few successful treatments have yet been discovered for the prophylaxis and treatment of hair loss in humans. In particular, no reliable treatment has yet been found for the treatment of telogen effluvium in humans. We have now made the surprising discovery that treatment with the essential amino acid lysine results in a substantial increase in hair growth in patients suffering from hair loss and in particular those suffering from telogen effluvium. Compositions for the treatment of hair loss are disclosed in US 5,470,876, US 5,133,958, US 5,122,369 and DE-A-3118882 which may contain lysine in combination with other ingredients. However, none of these documents discloses the use of L-lysine as an active principle in the prophylaxis or treatment of telogen effluvium.

The present invention provides the use of L-lysine in the manufacture of a medicament for the prophylaxis and treatment of hair loss in humans, provided that said L-lysine is not in the form of a complex with a transition metal and that said medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.

In particular, L-lysine is especially useful in the manufacture of a medicament for the treatment of telogen effluvium in humans.
The present invention also provides a method of treating hair loss in a subject, the method comprising the step of administering a medicament containing L-lysine to the subject, provided that said L-lysine is not in the form of a complex with a transition metal and that said medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.

The present invention further provides a method of treating telogen effluvium in a subject, the method comprising the step of administering L-lysine to the subject.

The present invention still further provides the use of a medicament containing L-lysine for the prophylaxis and treatment of hair loss in humans, provided that said L-lysine is not in the form of a complex with a transition metal and that said medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.

The present invention provides the use of L-lysine for the treatment of telogen effluvium in humans.

The present invention further provides a medicament for the treatment of hair loss in humans containing L-lysine, wherein the L-lysine is not in the
form of a complex with a transition metal and the medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.

Studies involving the administration according to the present invention of L-lysine to women suffering from increased hair shedding show a remarkable increase in scalp hair growth. This hair growth appears to involve an increase in the proportion of growing hair (anagen phase) and an accompanying decrease in the proportion of resting hair (telogen phase), an increase in the length of hair grown (shown as a decrease in the proportion of hair which is less than 30 mm in length) and a reduction in the amount of hair being shed from the scalp.

Typically, the L-lysine is administered in a daily dose of from 200 to 2000 mg, and more usually in a daily dose of 500 to 1500 mg, e.g. in the form of a 500 mg dose administered orally once, twice or three times a day. The L-lysine may be included in a formulation suitable for oral administration which also includes other essential elements, e.g. iron in the form of a salt or chelate such as ferrous sulphate, ferrous fumarate, ferrous gluconate, ferrous succinate, ferrous glycine sulphate or other chelated iron compounds (the typical daily dose of elemental iron being 14 mg to 300 mg), vitamin C (in a quantity equal to the iron content), and vitamin B₁₂ (the typical daily dose being 6μg to 200μg).

L-lysine may conveniently be administered orally, for example as tablets, capsules, granules, powders, mixtures, suspensions or syrups. These formulations can be prepared by conventional means and, if desired, the L-lysine may be mixed with any conventional additive, such an excipient, a binder, a disintegrating agent, a lubricant, a corrigent, a solubilising agent, a suspension aid, an emulsifying agent or a coating agent.
We have also discovered that administration of lysine to patients results in a dramatic increase in the efficacy of known treatments for genetic hair loss (which term covers a number of conditions variously referred to as androgen-dependent alopecia, androgenic alopecia, androgenetic alopecia, common baldness, female baldness, diffuse hair loss and male pattern baldness).

Thus, in a further aspect of the present invention there is provided a kit including a plurality of separate containers, each containing at least one active agent useful in a combination therapy for the treatment of genetic hair loss, wherein said kit includes L-lysine and at least one further active agent selected from minoxidil, antiandrogens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

There is also provided a therapeutic combination for the treatment of genetic hair loss comprising L-lysine and at least one further active agent selected from minoxidil, antiandrogens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

Typical examples of anti-androgens which can be used include cyproterone acetate, spironolactone, medroxyprogesterone acetate and flutamide which can, for example, be formulated for oral or topical administration. Type I, type II or mixed type I and type II 5α-reductase inhibitors can be used, e.g. finasteride. A typical example of a suitable corticosteroid is dexamethasone.

In a preferred embodiment, the kit comprises L-lysine and at least one further active agent selected from minoxidil and one or more anti-androgens, which are preferably chosen from cyproterone acetate, spironolactone and medroxyprogesterone acetate. In a particularly preferred embodiment, the kit comprises L-lysine which is formulated for oral administration and minoxidil which is formulated for topical application.

The co-administration of L-lysine with known treatments for genetic hair loss such as minoxidil and anti-androgens results in a significant improvement in the efficacy of the treatment. The reason for this improvement in efficacy is not currently understood.
Typically, L-lysine is administered in a daily dose of from 200 mg to 2000 mg, and preferably in a daily dose of 500 to 1500 mg, e.g. in the form of a 500 mg dose administered orally once, twice or three times a day. The known treatment for genetic hair loss (e.g. topical application of minoxidil to the scalp) is administered concurrently.

The surprising effect of L-lysine in the treatment of various forms of hair loss is illustrated by the following tests.

**Treatment of telogen effluvium in women**

Eight women were treated over a 16 week period with L-lysine, a 500 mg oral dose being given once, twice or three times a day (500 mg to 1500 mg total daily dose). Various biochemical investigations were performed on the women in the test programme before the start of the said programme and after 16 weeks of therapy, the details of which are given in Table 1 below together with the results obtained (mean values).

The effect of the administration of L-lysine on hair growth was determined by measuring three scalp hair variables - the percentage of hair in the anagen phase, the percentage of hair in the telogen phase and the percentage of hair less than 30 mm in length. These three variables were evaluated using the bio-assay known as the unit area trichogram (see Rushton et al, British Journal of Dermatology, 1990, 123, 187-197; Rushton et al, Clinical and Experimental Dermatology, 1991, 16, 188-192; and Rushton et al, Clinical Endocrinology, 1992, 36, 421-427). The values obtained at the start of the test and after sixteen weeks are shown in Table 2 below.
Table 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time - 0 weeks</th>
<th>Time - 16 weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemoglobin (hb)</td>
<td>12.2</td>
<td>12.6</td>
<td>ns</td>
</tr>
<tr>
<td>Serum ferritin</td>
<td>50.0</td>
<td>49.5</td>
<td>ns</td>
</tr>
<tr>
<td>serum zinc</td>
<td>13.6</td>
<td>13.9</td>
<td>ns</td>
</tr>
</tbody>
</table>

Blood based variables determined basally and after 16 weeks in eight female subjects complaining of increased hair shedding (mean values obtained, n=8). Statistical significance was assessed with Student's t-test for paired samples.

Table 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time - 0 weeks</th>
<th>Time - 16 weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anagen %</td>
<td>82.6</td>
<td>88.5</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Telogen %</td>
<td>17.4</td>
<td>11.5</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Hair &lt;30 mm %</td>
<td>17.4</td>
<td>12.4</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Hair variables determined basally and after 16 weeks in eight female subjects complaining of increased hair shedding (mean values obtained, n=8). Statistical significance was assessed with Wilcoxon signed rank test.

The results in Table 2 demonstrate clearly that the administration of L-lysine resulted in an increase in the proportion of hair in the anagen (growth) phase and a corresponding reduction in the proportion of hair in the telogen (resting) phase in women suffering from telogen effluvium. Additionally, there was a significant reduction in the percentage of hair less than 30 mm in length.

The results in Table 1 show that there was no significant change in the haemoglobin, serum ferritin or serum zinc levels in the blood between the start and finish of the treatment. It appears to be reasonable to conclude, therefore, that the significant increase in hair growth observed after the administration of L-lysine to women suffering from telogen effluvium was
not due to an increase in the blood iron or zinc level as a result of the administration of L-lysine.

For women suffering from telogen effluvium who have low iron or zinc stores, a further effect was observed, as shown in the following tests.

A group of women exhibiting chronic telogen effluvium who were being treated for reduced iron stores (serum ferritin concentrations below 40ng/ml) failed to achieve adequate increases of serum ferritin despite taking an iron supplement containing 50 to 100 mg of iron per day. However, when a daily L-lysine supplement of 1.0g or 1.5g was added to their existing daily iron supplement a significant (P<0.002) increase in serum ferritin concentration was observed (Table 3).

Table 3 Serum ferritin concentration basal and after 4 or 6 months of treatment with 50mg twice daily with and without L-lysine (1 to 1.5g) daily.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Baseline (ng/ml)</th>
<th>After 4 or 6 months of treatment (ng/ml)</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Iron only 100 mg/day</td>
<td>Iron (100 mg/day) + (Lysine 1 or 1.5g/day)</td>
<td></td>
</tr>
<tr>
<td>Subject 1</td>
<td>69</td>
<td>10.90</td>
<td>12.20</td>
<td>27.60</td>
</tr>
<tr>
<td>Subject 2</td>
<td>32</td>
<td>31.00</td>
<td>41.00</td>
<td>80.00</td>
</tr>
<tr>
<td>Subject 3</td>
<td>34</td>
<td>13.00</td>
<td>15.00</td>
<td>50.00</td>
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<tr>
<td>Subject 4</td>
<td>51</td>
<td>35.00</td>
<td>26.00</td>
<td>71.00</td>
</tr>
<tr>
<td>Subject 5</td>
<td>44</td>
<td>27.00</td>
<td>38.00</td>
<td>59.00</td>
</tr>
<tr>
<td>Subject 6</td>
<td>31</td>
<td>7.00</td>
<td>15.00</td>
<td>37.00</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>20.7</td>
<td>24.5</td>
<td>54.1</td>
</tr>
<tr>
<td>P=0.3 [iron only (NS)]</td>
<td>P&lt;0.002 (iron + lysine)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(statistical analysis paired Student's t test)
In Table 4 below serum zinc concentrations are presented for a group of women (n=10) in whom basal concentrations were below 11.8 μmol/L, i.e. within 10% of the lower limit of normal. The mean baseline concentration for this group was 10.28 μmol/L (range 9.0 μmol/L to 11.7 μmol/L). Each was treated with a daily supplement of L-lysine (1g to 1.5g) for 16 weeks, following which the mean serum zinc concentration had increased significantly (P<0.001) to 13.78 μmol/L (range 11.6 to 17.4 μmol/L).

Table 4. Changes in serum zinc concentration following daily supplementation with 1g - 1.5 g of L-lysine over a 16 week period.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Serum Zinc Time 0</th>
<th>Serum Zinc After 16 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject 1</td>
<td>11.7</td>
<td>17.4</td>
</tr>
<tr>
<td>Subject 2</td>
<td>10.4</td>
<td>16.1</td>
</tr>
<tr>
<td>Subject 3</td>
<td>10.6</td>
<td>11.6</td>
</tr>
<tr>
<td>Subject 4</td>
<td>9.3</td>
<td>11.8</td>
</tr>
<tr>
<td>Subject 5</td>
<td>11.7</td>
<td>13.3</td>
</tr>
<tr>
<td>Subject 6</td>
<td>9.0</td>
<td>13.8</td>
</tr>
<tr>
<td>Subject 7</td>
<td>9.5</td>
<td>14.5</td>
</tr>
<tr>
<td>Subject 8</td>
<td>9.0</td>
<td>14.0</td>
</tr>
<tr>
<td>Subject 9</td>
<td>10.3</td>
<td>12.3</td>
</tr>
<tr>
<td>Subject 10</td>
<td>11.3</td>
<td>13.0</td>
</tr>
<tr>
<td>Mean</td>
<td>10.28</td>
<td>13.78</td>
</tr>
</tbody>
</table>

P<0.001  paired t test
Treatment of women suffering from genetic hair loss

The effect of the administration of lysine on the efficacy of known treatments for genetic hair loss was investigated as follows.

Women suffering from genetic hair loss, all of whom had adequate iron stores within the normal range at the start of the test (i.e. serum ferritin levels of greater than 40 mg/ml), were divided into four groups.

The first group (17 women) was treated with minoxidil only (in the form of a topical formulation comprising 3% minoxidil by weight).

The second group (15 women) had a combined treatment of minoxidil (again as a topical formulation comprising 3% minoxidil by weight) and an oral anti-androgen chosen from cyproterone acetate, medroxyprogesterone and spironolactone. The first two anti-androgens were administered in combination with ethinylestradiol or an oral contraceptive. The particular anti-androgen administered was chosen on the basis of clinical need.

The third group (8 women) received a combined treatment of minoxidil (again as a topical formulation comprising 3% minoxidil by weight) and 500 to 1500 mg per day of L-lysine (administered orally).

The fourth group (13 women) received a combined treatment comprising minoxidil (again as a topical formulation comprising 3% minoxidil by weight), an oral anti-androgen (administered as to the second group above) and 500 to 1500 mg per day of L-lysine (administered orally). The results of these tests are shown in Table 5 below.
Table 5

<table>
<thead>
<tr>
<th>Response</th>
<th>Minoxidil Only</th>
<th>Minoxidil + Anti-androgens Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>9/17 (52.9%)</td>
<td>11/15 (73.0%)</td>
</tr>
<tr>
<td>=</td>
<td>6/17 (35.3%)</td>
<td>3/15 (20.0%)</td>
</tr>
<tr>
<td>-</td>
<td>2/17 (11.8%)</td>
<td>1/15 (6.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Response</th>
<th>L-lysine +Minoxidil</th>
<th>L-lysine + Minoxidil + Anti-androgens</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>8/8 (100%)</td>
<td>13/13 (100%)</td>
</tr>
<tr>
<td>=</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>-</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Response key
+ patient noticed an increase in hair quantity.
= patient did not see any change in hair quantity.
- patient felt there had been a decrease in hair quantity.

The results in Table 5 suggest that the co-administration of L-lysine to patients being treated for genetic hair loss with known treatments such as the topical administration of minoxidil and/or the oral administration of anti-androgens results in a considerable improvement in the efficacy of these known treatments.

When L-lysine is administered for the treatment of telogen effluvium in humans according to the present invention, a typical daily treatment regimen could include:

- L-lysine at 200mg to 2000mg per day;
- Elemental iron at 14mg to 300mg;
- Vitamin C at 14mg to 300mg; and
- Vitamin B12 at 3μg to 24μg.
Typically, the L-lysine may be administered as tablets or capsules containing the following ingredients:

- 200mg L-lysine
- 14mg Vitamin C
- 14mg iron (as ferrous glycine sulphate)
- 3μg Vitamin B₁₂

Typically, 200 mg L-lysine tablets are administered six times daily during the acute phase of telogen effluvium, four times daily during chronic phase and two times daily as a maintenance dose.

In the claims which follow and in the preceding summary of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprising" is used in the sense of "including", i.e. the features specified may be associated with further features in various embodiments of the invention.
THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. The use of L-lysine in the manufacture of a medicament for the prophylaxis and treatment of hair loss in humans, provided that said L-lysine is not in the form of a complex with a transition metal and that said medicament does not contain one or more of the following:  
   (i) a combination of trigonelline and vitamin B6;  
   (ii) pantothenic acid, either alone or in combination with divalent iron and methionine;  
   (iii) garlic oil or garlic extract;  
   (iv) oestrogenic hormones or derivatives thereof.

2. The use of L-lysine according to Claim 1 in the manufacture of a medicament for the treatment of hair loss in humans wherein the L-lysine is the sole active agent.

3. The use of L-lysine in the manufacture of a medicament for the treatment of telogen effluvium in humans.

4. The use according to claim 3, wherein said medicament consists of a daily dosage of 200 mg to 2000 mg of L-lysine and one or more of the following:  
   (i) an iron compound selected from the group consisting of iron (II) sulphate, iron (II) fumarate, iron (II) gluconate, iron (II) succinate, iron (II) glycine sulphate or another chelated iron compound, the daily dosage of elemental iron being 14 mg to 300 mg;  
   (ii) vitamin C in a daily dosage of 14 mg to 300 mg;  
   (iii) vitamin B12 in a daily dosage of 3μg to 24μg.

5. The use of a medicament containing L-lysine for the prophylaxis and treatment of hair loss in humans, provided that said L-lysine is not in the form of a complex with a
transition metal and that said medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.

6. The use of a medicament according to Claim 5 wherein the L-lysine is the sole active agent.

7. The use of L-lysine for the treatment of telogen effluvium in humans.

8. The use according to claim 7, wherein said medicament consists of a daily dosage of 200 mg to 2000 mg of L-lysine and one or more of the following:

(i) an iron compound selected from the group consisting of iron (II) sulphate, iron (II) fumarate, iron (II) gluconate, iron (II) succinate, iron (II) glycine sulphate or another chelated iron compound, the daily dosage of elemental iron being 14 mg to 300 mg;
(ii) vitamin C in a daily dosage of 14 mg to 300 mg;
(iii) vitamin B\textsubscript{12} in a daily dosage of 3μg to 24μg.

9. A method of treating hair loss in a subject, the method comprising the step of administering a medicament containing L-lysine to the subject, provided that said L-lysine is not in the form of a complex with a transition metal and that said medicament does not contain one or more of the following:

(i) a combination of trigonelline and vitamin B6;
(ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
(iii) garlic oil or garlic extract;
(iv) oestrogenic hormones or derivatives thereof.
10. The method according to Claim 9 wherein the L-lysine is the sole active agent in the medicament.

11. The method of treating telogen effluvium in a subject, the method comprising the step of administering L-lysine to the subject.

12. The method according to claim 11, wherein said medicament consists of a daily dosage of 200 mg to 2000 mg of L-lysine and one or more of the following:
   (i) an iron compound selected from the group consisting of iron (II) sulphate, iron (II) fumarate, iron (II) gluconate, iron (II) succinate, iron (II) glycine sulphate or another chelated iron compound, the daily dosage of elemental iron being 14 mg to 300 mg;
   (ii) vitamin C in a daily dosage of 14 mg to 300 mg;
   (iii) vitamin B12 in a daily dosage of 3μg to 24μg.

13. A medicament for the treatment of hair loss in humans containing L-lysine, wherein the L-lysine is not in the form of a complex with a transition metal and the medicament does not contain one or more of the following:
   (i) a combination of trigonelline and vitamin B6;
   (ii) pantothenic acid, either alone or in combination with divalent iron and methionine;
   (iii) garlic oil or garlic extract;
   (iv) oestrogenic hormones or derivatives thereof.

14. The medicament according to Claim 13 wherein the L-lysine is the sole active agent.

15. L-lysine when used for the treatment of telogen effluvium in humans.

16. A medicament for the prophylaxis or treatment of telogen effluvium in humans, said medicament containing from 200 mg to 2000 mg of L-lysine and one or more of the following:
(i) an iron compound selected from the group consisting of iron (II) sulphate, iron (II) fumarate, iron (II) gluconate, iron (II) succinate, iron (II) glycine sulphate or another chelated iron compound, the amount by weight of elemental iron being 14 mg to 300 mg;
(ii) from 14 mg to 300 mg of vitamin C; and
(iii) from 3μg to 24μg of vitamin B12.

17. A kit including a plurality of separate containers, each containing at least one active agent useful in a combination therapy for the treatment of genetic hair loss, wherein said kit includes L-lysine and at least one further active agent selected from minoxidil, anti-androgens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

18. A kit when used for the treatment of genetic hair loss, including L-lysine and at least one active agent selected from the group of active agents consisting of minoxidil, anti-androgens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

19. A kit according to Claim 17 or 18 wherein said anti-androgens are selected from cyproterone acetate, spironolactone and medroxyprogesterone acetate.

20. A kit according to Claim 19 wherein the anti-androgens are formulated for oral administration.

21. A kit according to Claim 17 or 18 comprising L-lysine and minoxidil.

22. A kit according to Claim 21 wherein the minoxidil is formulated for topical application.

23. Use of a kit according to any one of Claims 17 to 22 for the treatment of genetic hair loss.
24. A therapeutic combination for the treatment of genetic hair loss comprising L-lysine and at least one further active agent selected from minoxidil, anti-androgens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

25. A therapeutic combination when used for the treatment of genetic hair loss, said combination comprising L-lysine and at least one active agent selected from the group of active agents consisting of minoxidil, anti-androgens, 5α-reductase inhibitors, aromatase inhibitors and corticosteroids.

26. A therapeutic combination according to Claim 24 or 25 wherein said anti-androgens are selected from cyproterone acetate, spironolactone and medroxyprogesterone acetate.

27. A therapeutic combination according to Claim 24 or 25 comprising L-lysine and minoxidil.

28. A therapeutic combination according to Claim 27 wherein the minoxidil is formulated for topical application.

29. Use of a combination according to any one of Claims 24 to 28, for the treatment of genetic hair loss.

30. A therapeutic combination according to Claim 26 wherein the anti-androgens are formulated for oral administration.

31. Use of L-lysine in the manufacture of a medicament according to claim 1 for the prophylaxis and treatment of hair loss in humans, the use being substantially as described herein with reference to the accompanying examples.

32. Use of L-lysine in the manufacture of a medicament for the treatment of telogen effluvium in humans, the use being substantially as described herein with reference to the accompanying examples.
33. Use of a medicament according to claim 13 for the prophylaxis and treatment of hair loss in humans the use being substantially as described herein with reference to the accompanying examples.

34. The use of L-lysine for the treatment of telogen effluvium in humans, the use being substantially as described herein with reference to the accompanying examples.

35. A method of treating hair loss in a subject comprising the step of administering a medicament according to claim 13, the method being substantially as described herein with reference to the accompanying examples.

36. A method of treating telogen effluvium in a subject the method comprising the step of administering L-lysine in a subject and being substantially as described herein with reference to the accompanying examples.

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By their Patent Attorneys
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