

ANAGEN-PLUS® TREATMENT

Assessment of Clinical Effectiveness
in the **normalization of Anagen / Telogen relationship**
on adult males aged between 22 and 39 years old
diagnostically suffered by **androgenetic alopecia**
of I° and II° degree in Hamilton classification
performed by the
UNIVERSITY OF SIENA
Institute of Dermosifilopatic Clinic
Director: Prof. Lucio Andreassi

* Abstract

Is sent to **Villa Borghini®** Industry the final report of the survey performed by this University Clinic aimed to define the features of the analyzed treatment, named **ANAGEN - PLUS® TREATMENT** for hair loss.

The study has shown that the formulations took in consideration during this Clinical survey are in compliance with what is provided by the Law 713 of 11/10/1986 and have the requirements to be used in hair loss treatment.

Hair Loss is one of the issues more frequently detected by the observation of the Specialist Dermatologist. In fact this is a frequent and extremely widespread condition in both sexes that, not only involves the pilosebaceous apparatus, but for the patient represents even a psychological and social problem.

We can grossly distinguish between two different type of **alopecia: circumscribed** and **diffused**.

Androgenetic alopecia have to be singly considered, also called common baldness or seborrheic alopecia. At the present time we don't know yet perfectly the pathogenic mechanism of this condition on which the genetic predisposition has certainly a decisive influence.

Has been demonstrated an increased activity of 5 alfa-reductase, the enzyme responsible for converting testosterone to dihydrotestosterone in the genetically predisposed follicles. The result is that the duration times of anagen phase become shorter with a subsequent reduction of anagen/telogen relationship.

Upon request of **Villa Borghini®** Industry was performed by this University Clinic a deep survey aimed to define the features of the formulations of the above mentioned Industry, used in the hair treatment.

MATERIALS E METHODS

The Treatment named Anagen-Plus® is composed by a bottle of shampoo 250 ml and by 3 bottles of solution 200 ml/each.

The survey has been performed on adult males between 22 and 39 years old **diagnostically suffered by androgenetic alopecia** of I° e II° degree according to the Hamilton's classification.

At the beginning of the experimentation the patients had not been subjected to any type of treatment for alopecia in the previous three months and the **analyzed subjects lost till 350 hair per day**.

Moreover, the trichograms performed on the patients before the use of Anagen-Plus® Treatment showed an increase of hair in telogen phase higher than 20% and also of dystrophic hair up to 8%, these are the typical symptoms of androgenetic alopecia.

The **ANAGEN - PLUS® TREATMENT** was used on the patients for **120 days** in the following way:

1 – ANAGEN - PLUS® SHAMPOO was used **2 times per week** to wash hair and scalp, wetting well hair and scalp with lukewarm water and applying **ANAGEN - PLUS® SHAMPOO**, massaging until reach a durable and rich foam.

Then, the hair were thoroughly rinsed off and was made the second application of **ANAGEN - PLUS® SHAMPOO**, massaging until reach a durable and rich foam.

Then hair and scalp were thoroughly rinsed again and dried in a mild way with a towel. Then, the hair were disentangled with a wide toothed comb.

* The two washings with the **ANAGEN - PLUS® SHAMPOO** made as above mentioned, ensure a perfect cleaning of hair and scalp to allow to the subsequent application of **ANAGEN - PLUS® SOLUTION** to perform better its action.

2 – ANAGEN - PLUS® SOLUTION was continuously applied for 120 days, 5 ml per each day, both after the use of **ANAGEN - PLUS® SHAMPOO** and all the other days, taking care to put it in contact with scalp using the appropriate graduated dropper for the bottles of **ANAGEN - PLUS® SOLUTION** provided with the treatment.

* The **ANAGEN - PLUS® SOLUTION** does not need to be rinsed off.

The **trichograms**, performed according to the **Van Scott's Method** have been made and assessed with the microscope at basal time, after 60 days and after 120 days of Treatment use, taking every time 50 hair.

The Clinical results of the trichograms are shown in [Schedule 1](#).

Schedule 1

Assessment of Clinical Effectiveness
OF ANAGEN - PLUS® TREATMENT
 in Normalization / Increasing
 of Anagen / Telogen Relationship
 in **Patients suffered by Androgenetic Alopecia**,
 by the comparison of the trichograms before / after the use

N° Patient	Basal Time			60 days			120 days		
	Anagen/Telogen/Distrof.			Anagen/Telogen/Distrof.			Anagen/Telogen/Distrof.		
	%	%	%	%	%	%	%	%	%
▼	▼	▼	▼	▼	▼	▼	▼	▼	▼
1	76	20	4	78	20	2	82	16	2
2	68	24	8	74	22	4	82	14	4
3	72	26	2	74	24	2	82	18	0
4	64	30	6	68	28	4	80	18	2
5	70	28	2	74	24	2	84	14	2
6	62	34	4	64	32	4	62	32	6
7	68	28	4	74	24	2	82	14	4
8	62	32	6	64	30	6	76	18	6
9	68	30	2	76	22	2	82	16	2
10	70	28	2	78	20	2	82	16	2
11	60	36	4	64	32	4	62	32	6
12	72	22	6	76	18	6	80	14	6
13	66	30	4	68	28	4	80	18	2
14	64	30	6	62	30	8	72	18	10
15	78	20	2	78	18	4	84	14	2
16	78	20	2	78	18	4	80	16	4
17	74	22	4	78	18	4	78	16	6
18	68	26	6	-	-	-	-	-	-
19	70	24	6	70	24	6	76	20	4
20	74	18	8	78	16	6	82	14	4

The Clinical results shown in Schedule 1, have been performed with bulbar microscopy and they demonstrate the **gradual normalization of ANAGEN/TELOGEN relationship to hair loss physiological values.**

Even the [Seborrhea's trend](#), that represents a common issue that often goes with androgenetic alopecia, has been assessed on the basis of the Clinical Exam, performed at the beginning, after 60 days and after 120 days as shown in [Schedule 2](#).

Schedule 2

Clinical Effectiveness of **ANAGEN - PLUS® TREATMENT**
in Decreasing of seborrhoea,
in **Patients suffered by Androgenetic Alopecia**,
by the comparison of scalp sebometric values
measured with the sebometric device, before / after the use
of **Anagen-Plus® Shampoo** and **Anagen-Plus® Solution**

	Basal Time	Day 120
	▼	▼
Average Sebometric Values of the Patients	260,42	227,60

**The decreasing of the sebometric values
has been confirmed by the instrumental data**

Clinical Assessment of Safety
according to the **Strict Clinical-Pharmacological Protocols**
provided by the **Repeated Insult Patch Test**
of the two products that compose the
ANAGEN-PLUS® TREATMENT
Performed by the
UNIVERSITY OF SIENA
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* Abstract

ANAGEN - PLUS® SHAMPOO

Is certified that the product analyzed by this survey
is **incapable of evoking irritative or allergic reactions**
detectable using the **Repeated Insult Patch Test**

ANAGEN - PLUS® SOLUTION

Is certified that the product analyzed by this survey
is **incapable of evoking irritative or allergic reactions**
detectable using the **Repeated Insult Patch Test**

Final Clinical Opinion

UNIVERSITY OF SIENA
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Signs and symptoms, diagnostically assessed before the experimentation and after the use of **ANAGEN - PLUS® TREATMENT**, showed an **important hair loss decrease**, already assessable after 60 days and even more evident after 120 days, because **the trichograms clearly shown the gradual normalization of Anagen / Telogen relationship to physiological values of normality** with a number of hair in Telogen phase almost always less than 20%.

Moreover, in most of Patients even **the dystrophic hair are decreased**.

Even the Clinical Value gave to the **scalp itching**, is changed from a total value of 32 in the beginning phase to a final value of 9, showing an **important decrease** of this issue that, frequently, goes with the androgenetic alopecia status.

Moreover, the Clinical instrumental data have also shown a **decrease of sebometric values**, changed from a starting average value of 260,42 to a final value of 227,60.

During the **ANAGEN - PLUS® TREATMENT** experimentation period, all the Patients have been Clinically observed also for **Safety** checking and, **in no one case were detected irritative dermatitis, contact eczema or other**.

University of Siena
Institute of Dermosifilopatic Clinic
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