

NOVOXIDYL and *SEBOEX*

*Trichological and dermatological lines
for the treatment of the alopecia
and seborrheic dermatitis
of the scalp and the body*



December 2018

proderma
cosmeceutici s.r.l.s.

Via della Torre di Spizzichino, 202 - 00123 Roma Italy
ph. : +39 06.97844043
e-mail: info@prodermacosmeceutici.it

INDEX

Presentation of the lines	page	1
Products	page	3
The “plus” of the Novoxidyl and Seboex lines	page	6
Product brochures	page	9
Technical data sheets	page	25
Clinical data	page	35

Presentation of the lines

Proderma Cosmeceutici's **Novoxidyl line**, whose ownership had previously managed a pharmaceutical raw materials (vitamins and antibiotics) production plant, is born in 1987 with a product (Aminotril lotion in Italy) for the treatment of the androgenetic or areata alopecia, based on an innovative molecule developed in our laboratories: the Triaminodil®.

The Triaminodil® is the evolution of a pharmaceutical molecule (minoxidil), designed and patented by Upjohn for the treatment of the arterial hypertension, but that it had shown hirsutism as undesired collateral effect. Therefore, subsequently during the 80s, minoxidil was used as hair lotion with remarkable success. The worldwide pharmacists began to prepare the hair lotion, dissolving the minoxidil pills in an alcohol/water mixture.

In some cases these minoxidil lotions showed, above all in those to high active ingredient percentage, the collateral effect to lower the blood pressure also on healthy subjects.

Our idea has been that to utilize the chemical active sites of the minoxidil molecule in another molecule less active on the arterial pressure and, therefore, plus safe in the trichological use.

The result of this research has been the Triaminodil®, which is not a derivative of minoxidil, but a specific evolution for the application as trichological lotion with anti-fall activity in the treatment of the alopecia and telogen effluvium.

For these reasons Triaminodil® is a "parallel" of minoxidil and not a derivative with specific features for trichology and so an innovative molecule.

In short the advantages of the Triaminodil® in comparison with minoxidil are a greater safety of use to parity of anti-hair loss effect and the capacity to improve the hair appearance.

The success of the Aminotril lozione, now **Novoxidyl phytocomplex** for foreign markets, among the Italian dermatologists during the years was very promising and this has allowed us to prepare others two products based on Triaminodil®: **Novoxidyl shampoo**, anti-dandruff and anti-exfoliation shampoo with therapy maintenance activity during treatment

with the lotion and **Novoxidyl gel cream**, gel for face and body alopecia aerata treatment.

The **Novoxidyl shampoo soft**, even being a shampoo without Triaminodil®, present a important innovation: a new preparation technology based on water-soluble-oils (fluids) added to surfactants, that acts with great delicacy and an excellent balsamic activity on the hair and scalp, maintaining a very good cleanser action.

More recently has been developed the **Seboex line, lotion and cream**, for treatment of seborrhea and seborrheic dermatitis of scalp and body.

In the formulation development of Seboex line we tried to maintain the same ideas that they are to basis of other Proderma Cosmeceutici's lines, namely an innovative use of the molecules extensively tested for specific dermatological application.

Besides the use of Triaminodil® in the lotion, as rebalancing of pilosebaceous follicle, the Seboex formulas are based on presence of a phytoextract, *Cardiospermum halicacabum* glycolic extract, and two antifungals, Climbazole and Ciclopiroxolamine.

The first has high antiinflammatory and anti-pruriginous activities, both specific in presence of seborrhea, the seconds are particularly active against *Pityrosporum Ovale*, lipophilic yeast which in the case of seborrheic dermatitis plays an important role.

The successes of these lines in Italy has induced us to introduce them also on the foreign markets, choice that has proved winning.

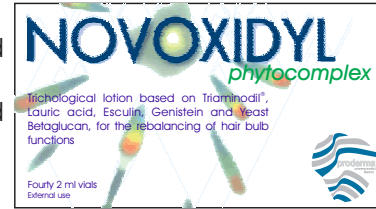
Products

Novoxidyl

trichological line

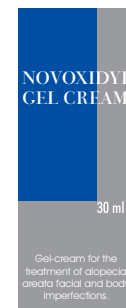
NOVOXIDYL PHYTOCOMPLEX

Hair lotion with Triaminodil®, esculin, lauric acid, aminodermine, genistein and betaglucan, to normalize the functions of pilosebaceous follicle. Novoxidyl fitocomplex is particularly recommended to stop the excessive hair loss due both androgenetic alopecia and telogen effluvium. Box of 40 or 20 pre-scratched 2 ml dark-glass vials with vial-breaker and dropper. Box of 12 pre-scratched 5 ml dark-glass vials with vial-breaker and dropper. 60 ml bottle with spray dispenser (no gas) in its case



NOVOXIDYL GEL CREAM

No-alcoholic gel for face and body alopecia areata treatment containing Triaminodil®, azelaic acid, carnitine and lipacides. Excellent skin sebum-balancing and softening power. 30 ml bottle with dispenser in its case



NOVOXIDYL SHAMPOO

Anti-dandruff creamy shampoo containing Triaminodil® and pyritione zinc. Excellent scalp anti-desquamation activity. Adjuvant in functional treatments against hair fall. Extra sweet washing basis containing anphoteric surfactants (betaines) and non ionic (acylglutamate).

200 ml bottle in its case



NOVOXIDYL SHAMPOO SOFT

Slightly foaming oily shampoo containing a mixture of hydrosoluble oils (fluids) and anphoteric surfactants. This innovative formulation makes the product highly biocompatible and balsamic on the hair and scalp, assuring a high quality standard of cleansing. Its use is advisable in pediatric childcare and neonatology, since it helps the dissolution of milk scab in addition to an extra mild deterston.

200 ml bottle in its case



Seboex

anti-seborrhea line

SEBOEX LOTION

Hair lotion with Triaminodil®, cardiospermum halicacabum glycolic extract, climbazole, ciclopiroxolamine, salicylic acid and vitamin E acetate to treatment of seborrea and seborrheic dermatitis of the scalp. In addition to anti-sebum action also it has an excellent anti-inflammatory and anti-itch activity. Box of fifteen pre-scratched 2 ml dark-glass vials. 30 ml bottle with spray dispenser in its case.



SEBOEX CREAM

Dermatological cream with cardiospermum halicacabum glycolic extract, climbazole, ciclopiroxolamine and vitamin E acetate to treatment of seborrea and seborrheic dermatitis of the body. Very good anti-inflammatory and antipruritic action.

30 ml aluminium tube in its case.



The “plus” of the Novoxidyl and Seboex lines

Triaminodil®

Triaminodil® is the evolution of a drug, minoxidil, created for the treatment of the systemic hypertension and which had showed to cause hirsutism as side effect and so it was used, with considerable success, to prepare an anti-hair loss lotion. The lotions on basis of minoxidil showed, especially those with high percentages of active principle, the side effect of lowering the arterial pressure even on several healthy subjects.

Triaminodil® is born in our laboratories and it has been patented and notified to Italian MOH as trichological molecule. It has proved, in topical use, the same anti hair loss activity of minoxidil but no systemic effect on arterial pressure and overall almost no side effects.

Lipacides

Molecule family patented by Givoudan-Lavirotte, which are the result of acylation between a fat acid and a vegetal origin amino-acid.

All Lipacides have a common feature: they show a very good skin anti redde-ning activity. Every single Lipacide add to this widespread characteristic its specific topical activity as: sebo-normalizer, specific disinfectant against acne bacteria, cutaneous acidifier, antiflogistic, dermoprotective and anti free radicals.

Acylglutamate

Surfactants derived from the fermentation of pyro-glutammic acid (patent Ajinomoto).

They have extraordinary characteristics as regards ratio between hydration, detergency/acidifying powers (very high level) and the primary skin irritation (almost nil).

In addition to this peculiarity which makes the acylglutammates definitely the best surfactants currently available, the excellent biocompatibility on skin and hair must be reminded. The skin is particularly soft and smooth, hair is easy to comb, shining and electrostatically poor.

Lauric Acid (n-dodecanoic acid)

This molecule is extract from *Serenoa Repens* and other plants. Several biochemical tests carried out on animal cells and human fiberblasts showed how lauric acid is an excellent action-inhibitor of 5-alpha reductase, the hair-fall.

Genistein

Genistein belongs to the isoflavones family and is present in soy.

Particularly important is its antioxidant action against free radicals, responsible for oxidative stress, and consequent "protection" activity of the hair.

The genistein as phytoestrogen has a positive effect on the follicular cycle, because it begins and prolongs the anagen phase.

Beta 1,3-1,6 glucan

The Beta 1.3 to 1.6 glucan is a protector from activity of oxidizing molecules and from oxidative stress. Free radicals can alter the hair cycle, with partial damage to proteins that compound the keratin.

The Beta 1.3 to 1.6 glucan stimulate the start of a new anagen phase in inert follicles.

Cardiospermum halicacabum glycolic extract

Active ingredient of plant extraction that in many European clinical trials has demonstrated a remarkable *anti-inflammatory and soothing actions on pruriginous states*.


Climbazole

Imidazolic molecule that has a dual activity extensively tested: antifungal specific for seborrheic dermatitis and cutaneous anti-inflammatory.

Ciclopiroxolamin

Piridonic antifungal that has demonstrated a remarkable ability to reduce the activity of the yeast *Pityrosporum Ovale*, lipophilic yeast which in the case of seborrheic dermatitis plays an important role.

Product brochures



ALOPECIA
and
TELOGEN EFFLUVIUM
MALE AND FEMALE

**FACED LIKE PINCERS WITH
COSMETOLOGICAL NATURALNESS**

TOPICAL TREATMENT



NOVOXYDYL *phyto*complex

based on Lauric acid, a similar finasteride, Triaminodil®, a similar minoxidil, Esculin, Beta 1.3 to 1.6 glucan and Genistein

A pincerlike technique aimed at:

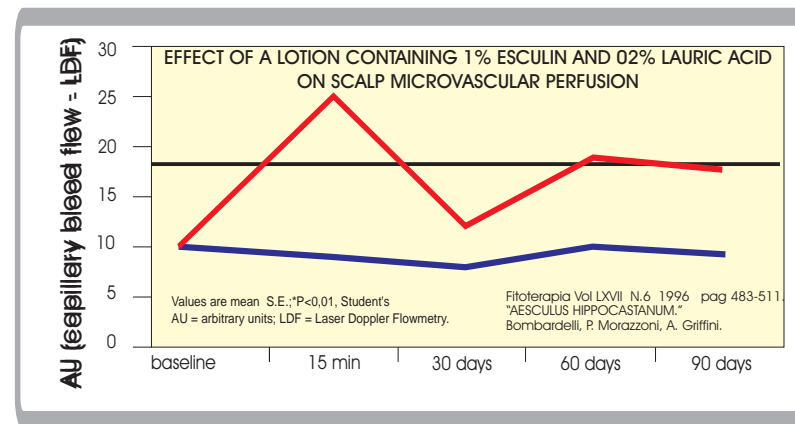
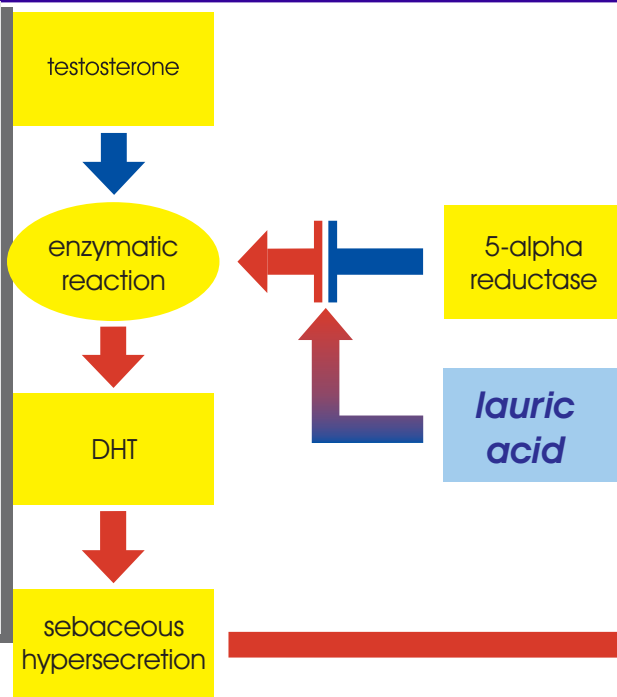
- improving the blood supply and the efficiency of microcirculation with more oxygenation of hair follicles.
- the inhibition of isoenzyme 5 - alpha - reductase activity, contrasting the conversion of testosterone to dihydrotestosterone
- improving the antioxidant activity versus oxidative stress from free radicals and the action phytoestrogenic
- the stimulation of a new anagen phase in inert hair follicles

LAURIC ACID (0,2%)

(C₁₂H₂₄O - acido dodecanoico da *Serenoa repens* alias *Sabal serrulata* o *Saw palmetto*)

He has shown in over 100 clinical trials since 1994, to counter the activity isoenzyme 5-alpha reductase (both type 5-alpha R1 and 5-alpha R2), inhibiting the conversion of testosterone into dihydrotestosterone (DHT) and so reducing hypersecretion of sebum. The decrease of DHT may prevent further hair loss in patients suffering from androgenetic alopecia.

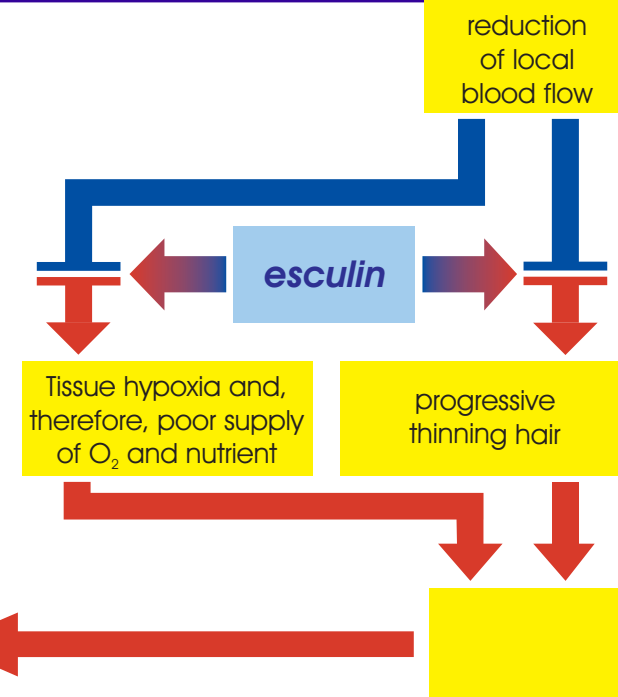
Lauric acid has therefore a finasteride similar action.



ESCULIN (1,0%)

(6-O-glucosil-7-idrossi-cumarina estratto dall'*Aesculus hippocastanum*)

Coumarinic which improves the microcirculation bringing more nutrients, oxygen and promotes activities of lauric acid and Triaminodil®, because it increases the blood concentration of these raw materials into microcirculation in the pilo sebaceous complex. It acts, therefore, increasing blood flow to the district when its reduction would lead to tissue hypoxia and a progressive thinning of the hair up to atrophy of the follicle pilo-sebaceous.



ALOPECIA and TELOGEN EFFLUVIUM MALE AND FEMALE

TRIAMINODIL® (1,5%)

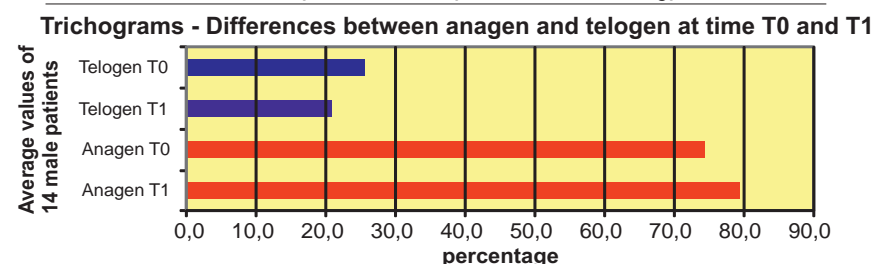
4 - pirrolidino - 2,6 diaminopirimidina 1 - ossido

Molecule developed in our laboratories, as an alternative to minoxidil such as specific raw material for treatment of non-specific alopecia and activator of VEGF (Vascular Endothelial Growth Factor).

It has shown in several tests in vivo and in vitro required for Ministerial notification and in clinical trials to which the lotion has been tested, a trichological activity completely identical to that of minoxidil without the unwanted central vasodilatory activity with relative blood pressure reduction.

Triaminodil® improves the local microcirculation, inhibit of abnormal hair loss not physiological, has a rebalancing action of the hair follicle for a better hair quality and beauty. Moreover Triaminodil® has proved to reduce excessive production of dandruff.

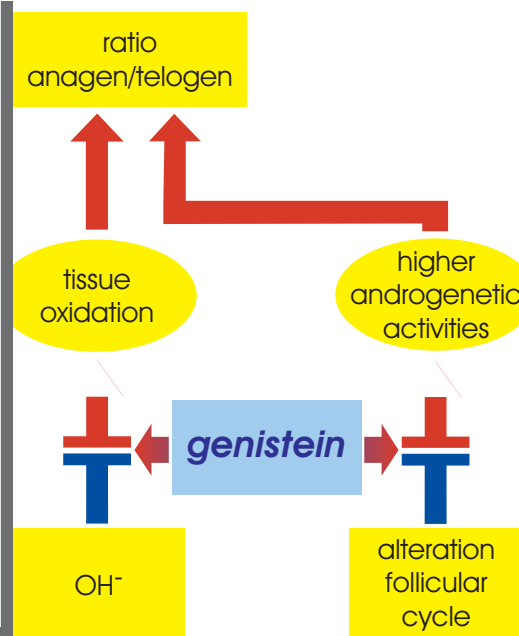
CLINICAL STUDY IN MALE AND FEMALE ANDROGENETIC ALOPECIA WITH A TOPICAL PRODUCT BASED ON TRIAMINODIL AND VITAMIN A
Melli M. C., Giorgini S., Farella V., Pollicarpi F., Zippil F., Cappugli F.
University of Florence - Department of Dermatology



GENISTEIN (0,25%)

(C₁₅H₁₀O₅ - 4',5,7-trihydroxyisoflavone)

Genistein belongs to the isoflavones family and is present in soy. This family of phytoestrogens bind to estrogen receptor, forming a receptor complex that functions in a similar way. Particularly important is its antioxidant action against free radicals responsible for oxidative stress, and its "protection" in the hair. The genistein as phytoestrogen has a positive effect on the follicular cycle, because it begins and prolongs the anagen phase.

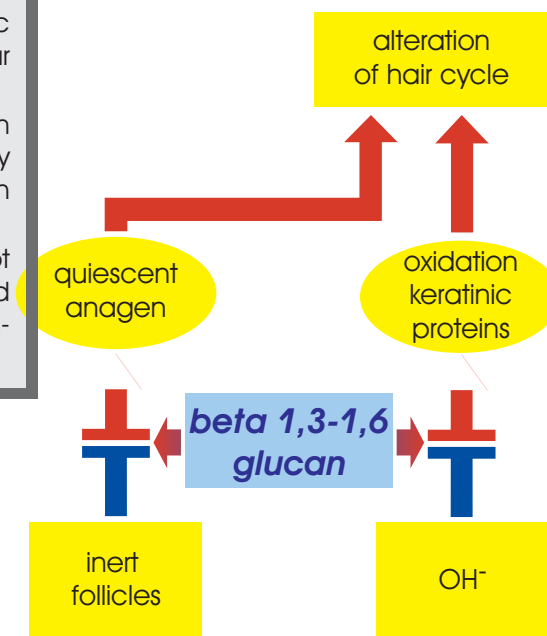


BETA 1,3-1,6 GLUCAN (0,25%)

(glucopolisaccaride estratto da lievito *Saccharomyces Cerevisiae*)

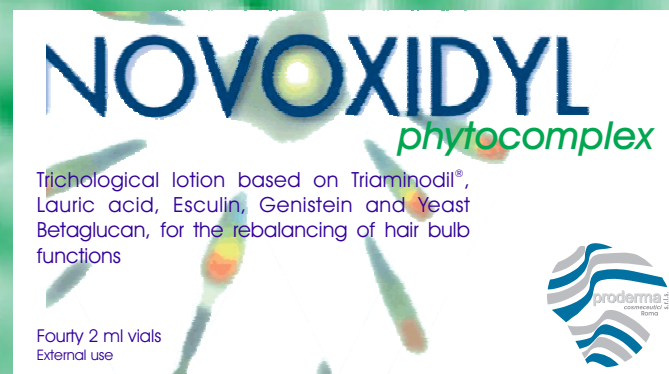
The beta 1.3 to 1.6 glucan is useful to protect fibroblasts and keratinocytes by oxidizing molecules and oxidative stress. Free radicals can alter the hair cycle, with partial damage to proteins that compound the keratin.

The Beta 1.3 to 1.6 glucan gives to the hair cells energy and nutrients and can also stimulate the start of a new anagen phase in inert follicles.



Use:
apply 1 ml with short hair or 2 ml in presence of long hair, twice daily on the scalp (avoiding to wet hair) with gentle massage. It is recommended to use regularly a shampoo as *Novoxidyl Shampoo*, nonionic and amphoteric syndet with excellent anti-dandruff and sebum normalizing activities. If it's not necessary an anti-dandruff or anti-sebum action, the best choice is *Novoxidyl shampoo soft*, extra mild cleanser with balsamic action. In case of long anti-dandruff treatment, it's possible use both shampoo alternately.

NOVOXIDYL
SHAMPOO



NOVOXIDYL GEL CREAM

gel cream for the treatment of the areata alopecia of the face and the body

Bibliography:

- 1) A. Rossi: "Risultati dell'utilizzo del 'Neo Aminotril Complesso' per uso topico" Centro per la Ricerca sulla Fisiologia e Patologia del Capello, Policlinico Universitario Umberto I, Roma - 2010.
- 2) Rampini E., Occeila C., Bleidl D.: "Valutazione dell'efficacia di un nuovo prodotto topico per la caduta dei capelli." *Chronica Dermat.*, 359-62, 1991.
- 3) Melli M. C., Giorgini S., Farella V., Policarpi f., Zippi P., Cappugi P.: "Studio clinico nella alopecia androgenetica maschile e femminile con un prodotto topico a base di Triaminodil e vitamina A." Istituto di Clinica Dermosifilopatica Università degli Studi di Firenze - 1990.
- 4) Capizzi R., Guerriero G., Landi F. L.: "Studio dell'efficacia clinica di un nuovo preparato topico per il trattamento del defluvium androgenetico e della dermatite seborroica." Istituto di Clinica Dermatologica Università Cattolica del Sacro Cuore - Roma, 1993.
- 5) Delos S, lehle C, Martin PM, Raynaud JP. (1994). "Inhibition of the activity of 'basic' 5 alpha-reductase (type 1) detected in DU 145 cells and expressed in insect cells". *J Steroid Biochem Mol Biol.* Mar; 48(4): 347-52.
- 6) Raynaud JP, Cousse H, Martin PM. D.R.I.T.T., Universite Pierre et Marie Curie, Paris, France. "Inhibition of type 1 and type 2 5alpha-reductase activity by free fatty acids, active ingredients of Permixon." *J Steroid Biochem Mol Biol.* 2002 Oct;82(2-3):233-9.
- 7) Bombardelli, P. Morazzoni, A. Griffini.: "AESCLUSUS HIPPOCASTANUM." *Fitoterapia* Vol LXXVII N.6 1996 pag 483- 511.
- 8) Morazzoni P., Bombardelli E. and Cristoni A. *Intemat. Federation Soc. Cosmet. Chemist (IFSCC) - Between Congress Conference, Montreux, Switzerland, September 18-21, 1995.*
- 9) K. J. McElwee, S. Niiyama, P. Freyschmidt-Paul, E. Wenzel, S. Kissling, J. P. Sundberg and R. Hoffmann: "Dietary soy oil content and soy-derived phytoestrogen genistein increase resistance to alopecia areata onset in C3H/HeJ mice" *Experimental Dermatology - Volume 12 Issue 1, Pages 30 - 36, 2003.*
- 10) Baek Seok Yun, Cho Won Hu, Park Won Seok, Shin Seong Yeon: "Composition for preventing falling out of the hair or promoting growth of the hair containing isoflavone aglycone genistein", 2004.
- 11) DKSK: "A Proprietary Beta-Glucan Supplement (Wellmune WGP) and the Incidence, Duration and Severity of Respiratory Infections in a Healthy Community-based Population: A Randomized, double-blind, placebo-controlled Trial", 2006.
- 12) B. J. Manners, A. J. Masson and J. C. Patterson: "The structure of a $\beta(1-3)$ D-glucan from yeast cell walls", *Biochem J*, 1973.
- 13) J. H. Saurat: "Dermatologia e malattie sessualmente trasmesse", ed. Masson, 2005.
- 14) L. Celleno: "Dermatologia e Cosmetologia", ed. Tecniche Nuove, 2008.

Presentation

Novoxidyl gel-cream is a preparation for the treatment of the telogen effluvium of the face and the body caused from several factors, like: physical and/or pharmacologist treatments, stress, seborrheic dermatitis, etc.

Novoxidyl gel-cream is born from the Proderma Cosmeceutici knowledge of the treatments techniques of the alopecia and telogen effluvium of the scalp, experience that has contributed to the success of its specific trichological products (Novoxidil phytocomplex, Novoxidyl shampoo, Novoxidyl shampoo soft and Seboex lotion).

The presentation in non-alcohol gel allows optimal absorption on the skin without greasiness and reduces the risks of irritation in the more sensitive subjects.

The formulation is based on a specific molecule patented by us and already employed in our products, Il Triaminodil®, and from three active ingredients: azelaic acid, l-carnitine and lipoaminoacid PVB.

Active ingredients

! Triaminodil®

Chemically it is an evolution of the minoxidil that during the clinical trials executed on our trichological products, has demonstrated a anti hair loss activity similar to the minoxidil, without having particular undesired side effects.

! Azelaic acid

This dicarbossilic acid has demonstrated in vitro a good capability to reduce the excess of sebum of the skin, thanks to its anti-mimicrobic power on the cutaneous microflora.

! l-Carnitine

Several authors have verified in vitro the capability of this amino acid to be a carrier of dicarbossilic acids, like azelaic acid, inside of the cell and, therefore, improving its bioavailability.

! Lipoaminoacid PVB

The lipoaminoacid they are the product of condensation between a fat acid and an amino acid. This technology (patent Givaudan - Lavirotte) allows to obtain various lipoaminoacids, each with its specific dermatological characteristics. The type PVB is the synthesis between palmitoic acid and the proteins of the grain and boast an optimal sweetening and calming action on the skin and an acidifying action in the piliferous zone.

Ingredients/ingredients:

aqua, hydroxypropyl guar, nonane dioic acid, pyrrolidinil diaminopyrimidine oxide, palmitoyl hydrolyzed wheat protein, carniti some, triethyl citrate, lactic acid, phenoxiethanol, methylparaben, ethylparaben, propylparaben, butylparaben, propylene glycol.

Instructions for use

It's recommended two applications to the day, morning - evening, massaging the part until complete absorption, for a period of 3-4 weeks

Packaging

30 ml bottle with dispenser in its case

Bibliografy:

- 1)- Rampini E., Occella C., Bleidl D.: "Valutazione dell'efficacia di un nuovo prodotto topico per la caduta dei capelli." *Chronica Dermat.*, 359-62, 1991
- 2)- Capizzi R., Guerriero G., Landi F. L.: "Studio dell'efficacia clinica di un nuovo preparato topico per il trattamento del defluvium androgenetico e della dermatite seborroica." *Istituto di Clinica Dermatologica Università Cattolica del Sacro Cuore - Roma* 1993
- 3)- Mayer da Silva A., Gollnick H., Detmar M., Gassmuller J., Perry A., Muller R. and Orfanos C. E.: "Effects of azelaic acid on sebaceous gland, sebum excretion rate and keratinization pattern in human skin." *Acta Derm. Venerol. (Stockh.)*, 143 (Suppl.), 20 - 30, - 1969
- 4)- Word B. J., Breathnach A. S., Robins E. J., Bhasin Y. P., Ethridge L., F.i.s.t., Nazzarro Porro M., Passi S.: "Effects of l-carnitine on cultured murine melanoma cells exposed to azelaic acid" *J. Invest. Dermatol.* 86, 4 - 1986

NOVOXIDYL SHAMPOO

Formulation

It's a zinc pyritione based tricho-cleanser which strongly active against dandruff and scalp desquamation.

Zinc pyritione is the molecule most used as anti-dandruff active ingredient thanks to very good capability to reduce the scalp scales production and the excess of cutaneous sebum.

Moreover the presence of a small quantity of Triaminodil, help the maintenance of treatment with Novoxidyl phytocomplex and it's synergistic with zinc pyritione.

The washing basis is made up by anphoteric (cocoamidobetaine) and not ionic (acylglutamate) surfactants, which grant a non-irritating and high quality washing activity of hair and scalp.

Characteristics

Novoxidyl shampoo therefore is a mild shampoo with a significant specific activity (against dandruff and scalp desquamation)

The mixture of surfactants used (non ionic and amphoteric) has an balanced combination of cleansing and not irritability on hair and scalp, which keep the hair manageable and gentle during styling or combing, without tangles and electrostatic charges.

Among surfactants we want to remember the Acylglutammate, produced by the fermentation of pyroglutammic acid, that are the best tensioactives now available on the world market, as the numerous clinical trials showed in the deteresion of highly damaged skin by contact dermatitis.

Ingredienti / Ingredients:

aqua, cocamidopropyl betaine, sodium laureth sulfate, sodium lauroyl glutamate, cocamide dea, zinc pyrithione, silica, glycerin, sodium pca, peg-15 coco polyamine, methylchloroisothiazolinone, methylisothiazolinone, parfum, pyrrolidinyl diaminopyrimidine oxide

Packaging

200 ml plastic bottle in its case

NOVOXIDYL SHAMPOO

Instructions for use:

Apply twice or three times a week, using lukewarm water and let the product act at least 1 minute on scalp.

Rinse thoroughly and, if using hair dryer, keep a lukewarm temperature.



NOVOXIDYL SHAMPOO *soft*

Formulation

A shampoo based on water-soluble oils and surfactants that acts with very delicacy on the hair and scalp. This innovative formulation warrant to Novoxidyl shampoo soft has new and superior features among functional hair cleansers.

Novoxidyl shampoo soft is the first preparation that unites in one product the advantages of an oil shampoo (high biocompatibility with the hair and skin and an excellent balsamic power on the hair) and the advantages of traditional products (foamy and good cleansing capacity even on oily hair with absence of rebound), without having their negative effects.

Characteristics

Novoxidyl shampoo soft is therefore suited to every type of hair, included that greasy, and shows considerable advantages when the hair is washed frequently, since it does not irritate the scalp and does not weaken the hair ends, but makes the hair perfectly combable, soft and shining.

Because of its delicate action, it is ideally suited to cleaning the hair during the application of scalp treatments and for small children, because it don't burn the eyes.

Besides, thanks to presence of the idrosoluble oil, it's able to dissolve the cradle cap.

Ingredienti / Ingredients:

aqua, PPG-12-buteth-16, disodium laureth solfosuccinate, cocamido-propyl betaine, sodium PCA, dimethicone, hydroxypropyl-methylcellulose, phenoxiethanol, methylparaben, ethylparaben, propylparaben, butylparaben, propylene glycol, parfum

Packaging

200 ml plastic bottle in its case.

NOVOXIDYL SHAMPOO *soft*

Instructions for use

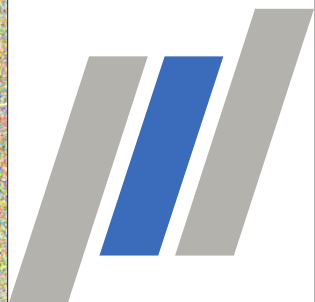
According the Specialist indications and/or the own habits, even daily, using lukewarm water and hair dryer.
Apply a small quantity for some minuts and rinse off.

NOVOXIDYL
SHAMPOO
soft



extra delicate
oily shampoo

NOVOXIDYL
SHAMPOO
soft



extra delicate
oily shampoo



SEBORRHEA AND SEBORRHEIC DERMATITIS

UNIQUE QUESTION FOR ONLY ONE ANSWER
FACING AT THREE HUNDRED SIXTY DEGREES
THE OBJECTIVE MAIN RESULTS

TOPICAL TREATMENT



SEBOEX CREAM AND LOTION

TARGETED TREATMENT VERSUS SEBORRHEA AND SEBORRHEIC DERMATITIS OF HAIRLESS AND HAIRY AREAS

THE PROBLEMS:

SEBORRHEA AND ALTERED
COMPOSITION OF SEBO

SCALY PATCHES
AND DANDRUFF

ACTIVE INGREDIENTS

SEBOEX CREAM and LOTION

CARDIOSPERMUM HALICACABUM GLYCOLIC EXTRACT (5.00%)

Active ingredient of plant extraction that in many European clinical trials has demonstrated a remarkable *anti-inflammatory and soothing actions on pruriginous states* also in the presence of violent and exudative inflammation. It was observed, moreover, that it acts on the erythematosus aspect of seborrheic dermatitis of the hairy and hairless areas.

VITAMIN E ACETATE (1.00%)

It *soothes inflammatory irritations* preventing the local appearance of scales. It acts as an antioxidant, considering that in this disease there is an alteration of the composition of sebum (rich in peroxides), tackling, therefore, oxidative stress. It reduces itching and gives softness to the skin.

CLIMBAZOLE (0.50%)

Imidazolic molecule that has a dual activity extensively tested: antifungal versus P. Oval in seborrheic dermatitis, in particular of the scalp, as it inhibits the ergosterol biosynthesis, and antiinflammatory, through action on the metabolism of arachidonic acid and, therefore, on the production of leukotrienes.

CICLOPIROXOLAMINE (0.50%)

Piridonic antifungal that acts by altering the permeability of the cytoplasmic membrane with consequent inhibition of the transport of aminoacids and ions necessary for cell growth of the yeast Pityrosporum Ovale, lipophilic yeast which in the case of seborrheic dermatitis plays an important role.

SEBOEX LOTION

to completion of the formulation for the piliferous zones:

TRIAMINODIL (1.00%)

Molecule developed in Proderma that can be considered a "parallel" of Minoxidil. It improve local microcirculation, balancing the vital functions of the hair bulb, as shown by several clinical trials. It's particularly indicated for the treatment of seborrheic dermatitis of the scalp and piliferous zones because it counteracts the excess dandruff, improving aesthetics.

SALICYLIC ACID (2.00%)

Beta-hydroxy acid that improves the skin appearance and condition, thanks to the micro-exfoliating action, breaking the S-S bonds of keratin. The use is aimed, therefore, versus the squamous component of seborrheic dermatitis of the scalp and piliferous zones. Furthermore, results on the pruritus component were also observed.



THE PRODERMA COSMECEUTICI'S COSMETIC RESEARCH TO FACE, NOT AS ALTERNATIVE BUT AS SUPPORT TO PHARMACOLOGICAL TREATMENT, SEBORRHEA AND SEBORRHEIC DERMATITIS TOGETHER WITH THE MOST COMMON SYMPTOMATIC PROBLEMS.





Apply 2 times a day half a vial of product (half in the morning and half in the evening) directly to the scalp and massage gently until completely absorbed. In case of thick or long hair, use a two vials, one in morning and one in evening.
The treatment involves an initial course of 15 days and then a maintenance period to be evaluated based on the individual patient and the individual response that, tentatively, may vary between 1 and 2 months with 4/5 vials per week
It's recommended the scalp cleansing three times a week with Aminotril SHAMPOO, extra gentle tricho-cleanser, based on betaine and acylglutamate surfactants, with sebum normalizing activities and specifically anti-dandruff, thanks to the presence of zinc pyrithione.

Directions for use



Apply 2-3 times daily on the affected area and gently massage until completely absorbed.
Protect the treated area with gauze.
The attack dose of two - three applications / day should be maintained for at least thirty days. Subsequently, based on the individual results obtained, it can recommend a maintenance period of about 1-2 months, reducing the applications.

We recommend cleaning the treated area with DEACNIL MILK least twice a day.
The use of a detergent biocompatible and highly specific for areas seborrheic, favors the action of Seboex cream. Deacnil milk guarantees the maximum hygiene of the treated area, thanks to the presence of a broad spectrum disinfectant, without altering the structure of hydrolipidic film.

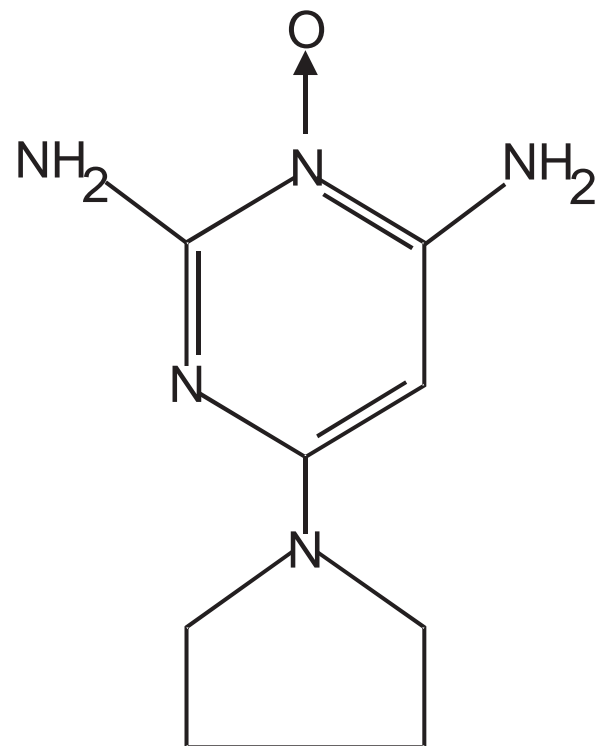
Bibliography:

- 1) A. Rossi: "Risultati dell'utilizzo del 'Neo Aminotril Complesso' per uso topico" Centro per la Ricerca sulla Fisiologia e Patologia del Capello, Policlinico Universitario Umberto I, Roma - 2010.
- 2) Capizzi R., Guerriero G., Landi F. L.: "Studio dell'efficacia clinica di un nuovo preparato topico per il trattamento del defluvium androgenetico e della dermatite seborroica." Istituto di Clinica Dermatologica Università Cattolica del Sacro Cuore - Roma, 1993.
- 3) J. H. Saurat: "Dermatologia e malattie sessualmente trasmesse", ed. Masson, 2005.
- 4) Leonardo Celleno: "Dermatologia e Cosmetologia", ed. Tecniche Nuove, 2008.
- 5) Roberto D'Onorio: "La terapia degli eczemi", ed. La Pelle, 2005.
- 6) Goodman & Gilman: "Le basi farmacologiche della terapia"; ed. Zanichelli, 1992.
- 7) Irwing M. Freedberg, Miguel R. Sanchez: "Diagnosi e terapia dermatologica attuale", ed. Piccin, 2003.
- 8) Jerome L. Shupack, Jonathan A. Gold: "Formulario dermatologico", ed. McGraw - Hill, 1991.
- 9) Josep del Hoyoi Calduch: "La pelle" ed. Edi - Ermes.

This scientific publication is reserved exclusively to Messrs. Physicians.
It cannot under any circumstances constitute advertising vehicle for the general public.

Technical data sheets

TRIAMINODIL®
4-pyrrolidine 2,6-diaminopyrimidine 1-oxide



COMPANY

Proderma Cosmeceutici srls
Via della Torre di Spizzichino, 202
00123 Rome – Italy
ph.: +39 06.97844043
email: info@prodermacosmeceutici.it

MOLECULAR FORMULA

C H N O

MOLECULAR WEIGHT

195,21

CAS NUMBER

55921-65-8

INCI NAME

pyrrolidinyl diaminopyrimidine oxide

the difference with minoxidil

Triaminodil®

- 4-pyrrolidine 2,6-diaminopyrimidine 1-oxide

Minoxidil

- 4-piperidine 2,6-diaminopyrimidine 1-oxide



TECHNICAL DATA SHEET

Product	Novoxidyl phytocomplex
Packaging	box (3 colours) of forty pre-scratched 2 ml dark-glass vials (1 colour) with vial-breaker and dropper or box (3 colour) of twelve pre-scratched 5 ml dark-glass vials (1 colour) with vial-breaker and dropper or 60 ml HDPE bottle (3 colour) with spray dispenser (hand pump – no gas) in its case (3 colour).
Activity	Anti-hair loss lotion caused by alopecia and telogen effluvium.
Presentation form	Hydroalcoholic solution slightly brown-coloured with alcohol smell.
Ingredients	alcohol denat, aqua, pyrrolidinil diaminopyrimidine oxide, esculin, methylchloroisothiazolinone, methylisothiazolinone, lauric acid, genistein, yeast betaglucon
Composition	Triaminodil®: 1,50% other active ingredients: 2,15%
Storage temp	15<T>30°C
Expiry time	36 months.
PAO	not expected because it's a single – dose packaging (vial).



TECHNICAL DATA SHEET

Product	Novoxidyl gel-cream
Packaging	30 ml HDPE bottle (2 colours) in its case (2 colours).
Activity	Treatment of loss of body or facial hair. The presentation form as gel allow the use in “vertical surface” without risk of dripping.
Presentation form	Aqueous gel, lightly-brown, with characteristic slight sulfur compound smell.
Ingredients	aqua, hydroxypropyl guar, nonane dioic acid, pyrrolidinil diaminopyrimidine oxide, palmitoyl hydrolyzed wheat protein, carnitine, triethyl citrate, lactic acid, phenoxyethanol, methylparaben, ethylparaben, propylparaben, butylparaben, propylene glycol
Composition	Azelaic acid: 2,00% Triaminodil®: 2,00% Lipacide: 0,50% other ingredients: 3,55% (as dried substance)
Storage temp	18<T>30°C
Expiry time	Over 30 months.
PAO	12 months.



TECHNICAL DATA SHEET

Product	Novoxidyl shampoo
Packaging	200 ml white HDPE bottle (1 colours) with "disk top" plastic cap in its case (3 colours). Package insert.
Activity	Anti-dandruff and sebo-rebalancing shampoo. Excellent as Novoxidyl fitocomplex adjuvant. High cleaning activity of skin flakes.
Presentation form	White creamy shampoo slightly scented. This presentation form is a "false" cream because it's thickened also by silica that gives it an aspect white and creamy. In this mode is avoided that zinc pyrithione precipitate into the bottle being insoluble in water. With this technique is possible to maintain in suspension the insoluble substances for long time (over one year at room temperature)
Ingredients	aqua, cocamidopropyl betaine, sodium laureth sulfate, sodium lauroyl glutamate, cocamide dea, zinc pyrithione, silica, glycerin, sodium pca, peg-15 coco polyamine, ethylchloroisoithiazolinone, methylisothiazolinone, parfum, pyrrolidinil diaminopyrimidine oxide
Composition	total surfactants (anionic, amphoteric and not ionic): 14,7% (as dried substance) zinc pyrihione: 0,75% (as dried substance) Triaminodil®: 0,08% other ingredients: 4,25% (as dried substance)
Storage temp	20<T>30°C
Expiry time	Over 30 months.
PAO	12 months.



TECHNICAL DATA SHEET

Product	Novoxidyl shampoo soft
Packaging	200 ml HDPE bottle (3 colours) with "disk top" plastic cap, in its case (3 colours).
Activity	Extra-soft shampoo based on blend of hydrosoluble oils (fluids) and amphoteric surfactants.
Presentation form	Colorless solution little foaming and slightly scented.
Ingredients	aqua, PPG-12-buteth-16, disodium laureth solfosuccinate, cocamidopropyl betaine, sodium PCA, dimethicone, hydroxypropyl-methylcellulose, phenoxyethanol, methylparaben, ethylparaben, propylparaben, butylparaben, propylene glycol, parfum
Composition	Hydrosoluble oils: 20% Total surfactants (amphoteric, anionic): 6.9% (as dried substance) Other active ingredients: 0,5% (as dried substance)
Storage temp	15<T>30°C
Expiry time	Over 30 months.
PAO	12 months.



TECHNICAL DATA SHEET

Product	Seboex cream
Packaging	30 ml aluminium tube (3 colours) in its case (3 colours)
Activity	cream for dermocosmetic treatment of seborrhoea and seborrheic dermatitis of hairless areas.
Presentation form	O/W cream, off-white, slightly scented.
Ingredients	aqua, isopropylmyristate, glycine soja oil, cardiospermum halicacabum extract, propylene glycol, cetearyl alcohol, peg-100 stearate, glyceryl stearate, sodium pca, tocopheryl acetate, glycerin dimethicone, climbazole, ciclopirox olamine, parfum, carbomer, imidazolidinylurea, triethanolamine, tetrasodium EDTA, benzyl alcohol, dehydroacetic acid, methylchloroisothiazolinone, methylisothiazolinone, magnesium, chloride, magnesium, nitrate
Composition	Cardiospermum halicacabum glycolic extract: 5,00% Climbazole: 0,50% Cyclopiroxolamine: 0,50% other active ingredients: 4,00%
Storage temp	15<T>30°C
Expiry time	36 months.
PAO	12 months.



TECHNICAL DATA SHEET

Product	Seboex lotion
Packaging	box of fifteen pre-scratched 2 ml dark-glass vials with vial-breaker and dropper (box 3 colours) or 30 ml HDPE bottle (3 color) with spray dispenser (no gas) in its case. (3 colours)
Activity	lotion for dermocosmetic treatment of scalp seborrhoea and seborrheic dermatitis
Presentation form	Hydroalcoholic solution slightly brown-colored with alcohol smell .
Ingredients	alcohol denat, aqua, cardiospermum halicacabum, tocopherol, pyrrolidinil daminopyrimidine oxide, sodium pca, methylchloroisothiazolinone, methylisothiazolinone, climbazole, ciclopirox olamine, salicylic aci
Composition	Triaminodil®: 1,00% Cardiospermum halicacabum glycolic extract: 5,00% Cyclopiroxolamine: 0,50% Climbazole: 0,50% Salicylic acid: 2,00% other active ingredients: 3,00%
Storage temp	15<T>30°C
Expiry time	36 months.
PAO	12 months (bottle) not provided (vials – single dose)

Clinical data

Please note:

the following data were extracted from clinical trials done on precedent versions of products with different formulas compared to current products, but the Triaminodil[®] is always present also if with different concentrations.

We have wanted to add these clinical data at the present publication with the intent to prove the effectiveness and absence of side effects of Triaminodil[®].

The original clinical trials are available upon request.

1. “Studio dell’efficacia clinica di un nuovo preparato topico per il trattamento del defluvium androgenetico e della dermatite seborroica”

R. Capizzi, G. Guerriero, F. L. Landi

Istituto di Clinica Dermatologica – Università Cattolica del Sacro Cuore – Roma - 1992

Clinical trial of a topical product for domestic market based on Triaminodil® 1,5% for treatment of androgenetic defluvium and seborrheic dermatitis. Catholic University of Rome - 1992

Results after 4 months of treatment

N° patients	stationary	improvement	remarkable improvement
Male: 28	14		14
Female: 14	0	3	11

2. “Studio clinico nella alopecia androgenetica maschile e femminile con un prodotto topico a base di Triaminodil® e vitamina A”

Melli M. C., Giorgini S., Farella V., Policarpi F., Zippi P., Cappugi P.

Istituto di Clinica Dermatologica – Università degli Studi di Firenze - 1990

Clinical trial of a topical product for domestic market based on Triaminodil® 0,8% for treatment of male and female androgenetic alopecia. University of Florence - 1990

Results after 3 months of treatment

N° patients	stationary	improvement	remarkable improvement
Male: 14	5	8	1
Female: 16	0	16	0

3. “Valutazione dell’efficacia di un nuovo prodotto topico per la cura dei capelli”

E. Rampini, C. Ocella, D. Bleidl

Istituto Giannina Gaslini – Genova - 1989

Clinical trial for evaluation of the effectiveness of a product for domestic market based on Triaminodil® 0,8%

Giannina Gaslini Institut of Genoa - 1989

Results after 6 months of treatment

N° patients	stationary	improvement	remarkable improvement
Male: 30	21	0	9
Female: 0	0	0	0

4. “Risultati dell’utilizzo di ‘Neo Aminotril Complesso’ per uso topico Trial clinico”

A. Rossi

Policlinico Universitario Umberto I – Roma - Centro per la Ricerca sulla Fisiologia e Patologia del Capello - 2010

Clinical trial of a topical product for domestic market based on Triaminodil® 1,5%. Results of use.

University of Rome - Center for Research on the Physiology and Pathology of Hair - 2010

Results after 6 months of treatment

N° patients	stationary	improvement	remarkable improvement
Male/Female: 20	3	9	8