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TECHNICAL DATA SHEET

ANTI-CELLULITE COMPLEX / A / HGL / CA11 /



Trade Name: ANTI-CELLULITE COMPLEX / A / HGL / CA11 /

Product Code: CACAHLCA11.

INCI Name: AQUA, GLYCERIN, ALGAE EXTRACT, PAULLINIA CUPANA SEED EXTRACT, AESCULUS HIPPOCASTANUM EXTRACT, POTASSIUM SORBATE.

INCI Status: Conforms.

REACH Status: Low Volume Exemption.

CAS Number: 7732-18-5; 56-81-5; 92128-82-0 / 68917-51-1; 84929-28-2; 8053-39-2; 24634-61-5 / 590-00-1.

EC Number: 231-791-2; 200-289-5; 295-780-4; 284-512-1; 232-497-7; 246-376-1.

Origin: GLYCERIN: Vegetable origin.

ALGAE EXTRACT, PAULLINIA CUPANA SEED EXTRACT, AESCULUS HIPPOCASTANUM EXTRACT: Vegetable origin.

POTASSIUM SORBATE: Synthetic origin.

Processing: GMO Free. / No Ethoxylation. / No Irradiation. / No Sulphonation. / No BSE/TSE. / No CMR. / No SVHC. / No Nanomaterial. / No DEG. / No DEHP. / No Formaldehyde. / No Phthalates. /

Additives: Preservatives: Potassium sorbate. Paraben Free. / Antioxidants: None. / Other additives: None.

Solvents Used: Water and glycerin.

Appearance: Clear or slightly opalescent liquid.

Colour: Characteristic (yellowish to deep brown).

Odour: Characteristic.

Specific gravity: 1,050 - 1,300 g/cm³ (20°C approx.).

Direct pH value: 4,5 - 6,5 (20°C approx.).

Soluble/ Miscible: Water. Surfactants. Hydroalcoholic, hydroglyceric and hydroglycolic mixtures.

Ecological Information: Sustainable.

Microbial Count: **Total aerobics:** Max. 300 microorganisms / gram.

Fungi and yeasts: Max. 200 microorganisms / gram.

Pathogens: Total absence in 1 gram.

Suggested Use Levels: 2,0 – 10,0%.

Suggested Applications: Anti-cellulite products.

Properties: Anti-cellulite.

Industrial packing: 1Kg., 5Kg., 25Kg., 225Kg.

Storage conditions: It is very important to keep the product in well closed containers, away from direct sunlight at temperatures not over 15°C. In case of not having refrigerators, store the product in the coolest and free from artificial light area.

Bibliography: - Atlas Ilustrado de Plantas Medicinales y Curativas, Ed. Susaeta.

- Dumont's grosse Kräuter Enzyklopädie.

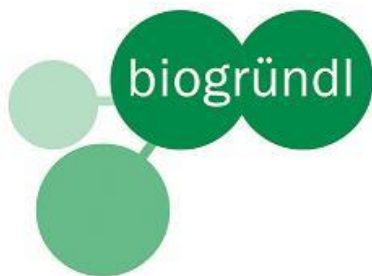
- Fitocosméticos ALVAREZ CRUZ i BAGUE SERRANO.

- Gran enciclopedia de las plantas medicinales, BERDONCES i SERRA.

- Plantas medicinales, FONT i QUER.

- Proserpio G., Martelli A., Patri GF.; Elementi di Fitocosmeci; Ed. Sepem / Milano 1983.

- Websites.



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OVERVIEW

Although the main treatment of both physical disorders is medical, within the specialties of endocrinology and dermatology, cosmetology can help and, of course, is already doing so, complementing and boosting medical treatment. Cosmetology plays an indispensable role in this area: medicine can achieve, for example, slimming in general, but localized in a particular part of the body, it relies on cosmetology.

HYDRODYSTROPHY

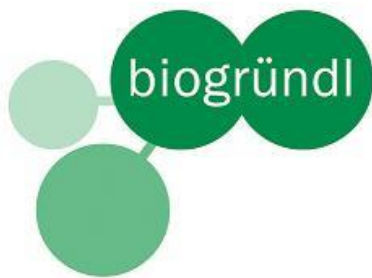
Hydrodystrophy or cellulite can be defined as a connective tissue alteration of ill-defined nature, consisting of interstitial liquid accumulation. Cellulite is characterized by the appearance of nodes that can be perceived when pressing or pinching, generally producing a painful feeling. It is about an endocrine process manifestation that starts with the inflammation of said tissue and ends in water retention, with the resulting volume increase at the connective tissue.

Connective tissue is made up of fibres and interfibrillar substances. Those are of protein nature, divided into three types: collagenic, elastic and reticular. They have the purpose to connect and support the connective tissue. The interfibrillar substances are of carbohydrate type and they form an amorphous material as jelly, composed by acid mucopolysaccharides (hyaluronic acid) and sulphated mucopolysaccharides (chondroitin sulfate). Their function is to keep turgid the connective tissue, and, also, to disseminate nutritional substances from blood capillaries to conjunctive tissue cells.

In some abnormal conditions, these mucopolysaccharides are extraordinarily polymerized, becoming eager for water, producing retention and the subsequent oedema in the connective tissue. Although the causes that produce polymerization of mucopolysaccharides are not known yet, advances on endocrinology have demonstrated considerable influence exerted by hormones over the connective tissue. Some act directly (corticoids), others indirectly by means of mucopolysaccharase inhibitors. Some of them have a polymerizing action (estrogens, glucocorticoids), while others have a depolymerizing action (dihydrocorticosterone, thyroxine, progesterone). All of this has made several authors to think that the degree of mucopolysaccharides polymerization depends directly on hormones, although they also lay under many other influences.

Clinically, these alterations of the connective tissue can be represented as follows:

- Flood of the conjunctive spaces.
- Imbibition of all tissues, especially of the adipose one.
- Oedema, with tissue swelling, caused by excess of tissular liquid.



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Bad oxygenation, deficient nutrition and cell intoxication bring several characteristic symptoms, as hypothermia in the affected areas. Very frequently, it can be proved that cellulite treatment produces an improvement of the general good health, making disappear vague symptoms of asthenia and general discomfort.

HYDRODYSTROPHIE TREATMENT

HOW TO TREAT HYDRODYSTROPHIE

Cellulite is, because of its nature, a disease impossible to be solved by itself. There is no spontaneous cure. Its treatment must be double-sided: by means of infiltrations and topical. The first one corresponds to the doctor and will be the main one; the topical treatment belongs completely to Cosmetology field.

It is completely useless to start a weight loss diet in the case of cellulite; normal areas are stylized and cellulite malformations become even more noticeable.

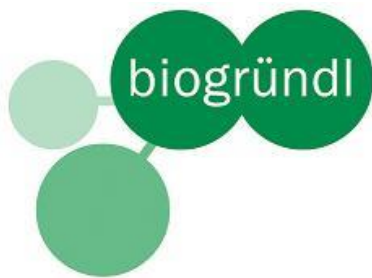
MESOTHERAPY TREATMENTS

Medical treatment based on the application of mucopolysaccharide enzymes. These enzymes act on the mucopolysaccharides of the main substance, they help the substance to recover its natural fluidity, dissociating the fibers into elemental fibrils and releasing retained water in the fundamental substance. Released water will be eliminated, afterwards, through adequate medicine: generally, with diuretics and potassium salts which move the sodium and do not retain water in the tissues.

The two most used enzymes are thiomucase and hyaluronidase. They are used in injectable ampoules to be administered by infiltration into the cellulite nodes.

TOPICAL TREATMENT

The topical or external treatments commonly applied for cellulite treatment are: physiotherapeutical and cosmetological.



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PHYSIOTHERAPEUTICAL TREATMENTS

They imply the utilization of physical or mechanical means for the treatment of the disease. It is therefore an authentic external medication. They produce a general organic relaxation very useful for the cellulite treatment. They increase the temperature in the areas under treatment, and stimulate blood circulation, improving the absorption mechanisms of the nutritional products and the rejection of the waste.

The main physiotherapeutical means are the following:

- Ultrasounds
- Excitomotor electrical currents
- High and low frequency static currents.
- Manual massages
- Mechanical massages
- Hydrotherapy

COSMETIC TREATMENT

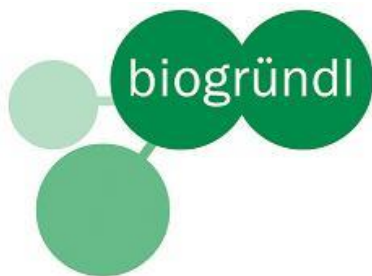
To achieve greater efficiency of physiotherapeutic treatment, there are various cosmetics, that enhance the mechanical action of massage, incorporating anti-cellulite active principles.

- a. Mucopolysaccharidase enzymes, that is to say, hyaluronidase and thyomucase.
- b. Extract of thyroids, or thyroxine, since one possible cause of cellulite, could be due to poor functioning of the thyroid gland.
- c. Plant extracts.
- d. Some organic compounds such as caffeine, theophylline, or carnitine which accelerate the metabolism of skin tissue.
- e. Iodide organic and inorganic compounds from natural or synthetic origin.

The mentioned active ingredients to treat cellulite by applying topical methods, do not all of them present demonstrable efficacy in practice.

Mesotherapy, that is to say, infiltrations with mucopolysaccharidase enzymes, is the most effective method for the treatment of cellulite. However, it is quite annoying and has to be applied, strictly and exclusively, under medical surveillance. It is not, therefore, a cosmetic procedure. Topically, it can be considered as a cosmetic treatment, but its efficiency is very low.

Physiotherapeutical methods are generally effective, but most of the active substances included in the means for massage, present a doubtful or even null efficiency.



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USE AND DOSAGE

Taking into account the exposed problems, BIOGRÜNDL, S.L. after extensive research on the subject of anti-cellulite preparations, presents its new ANTI-CELLULITE COMPLEX consisting on the following components:

- Brown algae extract with high iodine content.
- Horse chestnut extract (*Aesculus hippocastanum*), tree whose leaves are very rich in flavonoids and saponins (escin), with a great influence on peripheric circulation (P vitamin effect).
- Guarana extract (*Paullinia cupana*), a climber of the Amazonia jungle, extraordinarily rich in caffeine and saponosides content, that increases metabolism.

These three actives of ANTI-CELLULITE COMPLEX by BIOGRÜNDL, S.L., properly balanced, shows proven action on the rigidity and sclerosis of connective tissue, causing a decrease in swelling caused by cellulite nodules, drainage of water and lipids accumulated, as well as, softening effect on skin folds. All of this translates into remarkable anticongestive and revitalizing effect of connective tissue.

ANTI-CELLULITE COMPLEX by BIOGRÜNDL, S.L. is suitable for slimming and anti-cellulite treatments. For that purpose, it is necessary to include in an appropriate excipient that can be a lotion, a gel or an emulsion, in proportions ranging from 5 to 20%. In massage creams should be added between 2 and 5%. It can also be added to foaming gels with anti-cellulite effect in the proportion from 5 to 10%.

If turbidity is observed, it is advisable to previously dissolve the product in a portion of the water provided to manufacture the final product and filter after 12-24 hours.



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PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear or slightly opalescent liquid.

Colour: Characteristic (yellowish to deep brown).

Odour: Characteristic.

Direct pH value: 4,5 - 6,5 (20°C approx.).

Specific gravity: 1,050 - 1,300 g/cm³ (20°C approx.).

Solubility in water: Fully soluble (20°C approx.).

Solubility in other solvents: Insoluble in organic solvents and lipids. Soluble in surfactants, hydroalcoholic, hydroglyceric and hydroglycolic mixtures.

Heavy metals: No more than 5 mg/Kg.

Sulfated ash: No more than 0,01%.

Chlorides: No more than 0,007%.

Sulfates: No more than 0,002%.

Other information: None.

Total aerobics: Max. 300 microorganisms / gram.

Fungi and yeasts: Max. 200 microorganisms / gram.

Pathogens: Total absence in 1 gram.

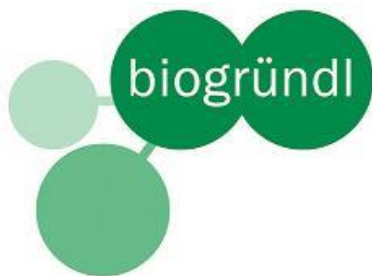
Organic iodine content: Between 0,05 and 0,3%.

% Iodine calculation: Weigh accurately around 1g. into a crucible of Pt or Ni, previously calcinated. Add 2ml. of KOH at 10% and 1ml. of sodium bisulfite at 20%. Dry at 100°C in an oven and reduce to ashes over direct heat in a muffle at 600°C during 30 minutes. Leave to cool and dissolve the obtained ashes with three successive portions of 15ml. of distilled water, passing them into a 250ml. erlenmeyer.

Add 2ml. of nitric acid at 10%, 1ml. of ammonium ferric sulfate at 40% and 10ml. of silver nitrate 0,1 n, exactly measured. Titrate with ammonium sulphocianure 0,1 n to a reddish color.

$$\% \text{ Iodine} = (10 - n) \times 1.27$$

Where **n** is the ml. of ammonium sulphocianure spent on the valoration.



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DERMATOLOGY INNOCUOUSNESS

It was performed by the patch test (Patch test) on 10 volunteers. To this purpose, 20% ANTI-CELLULITE COMPLEX by BIOGRÜNDL, S.L., was added to an O/W emulsion; 0,5g. of this emulsion was poured over the patch and attached on the forearm. It is thus maintained for 24, 48 and 72 hours, after which, the given reaction was evaluated, according to the following table of values:

1. No erythema.
2. Slight erythema.
3. Well defined erythema.
4. Severe erythema.

The result was absence of erythema on the 10 volunteers.

On the recommended concentrations, the product is skin innocuous.

STORAGE CONDITIONS

It is very important to keep the product in well closed containers, away from direct sunlight at temperatures not over 15°C. In case of not having refrigerators, store the product in the coolest and free from artificial light area.

INCI DENOMINATION

AQUA, GLYCERIN, ALGAE EXTRACT, PAULLINIA CUPANA SEED EXTRACT, AESCULUS HIPPOCASTANUM EXTRACT, POTASSIUM SORBATE.

EFFECTIVENESS TEST

Assay: Double blind spot trial and subsequent cosmetic evaluation.

Assayed parameters: Anti-cellulite action.

N (volunteers): 30 (25 ♀ and 5 ♂).

Age (volunteers): 25 – 48 years old.

Left side part to be treated:

Placebo, 30 volunteers, suitable cosmetic base.

Right side part to be treated:

ANTI-CELLULITE COMPLEX 2%, 15 volunteers, suitable cosmetic base.

Right side part to be treated:

ANTI-CELLULITE COMPLEX 5%, 15 volunteers, suitable cosmetic base.

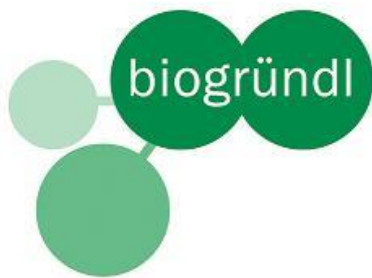


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Assayed parameter:

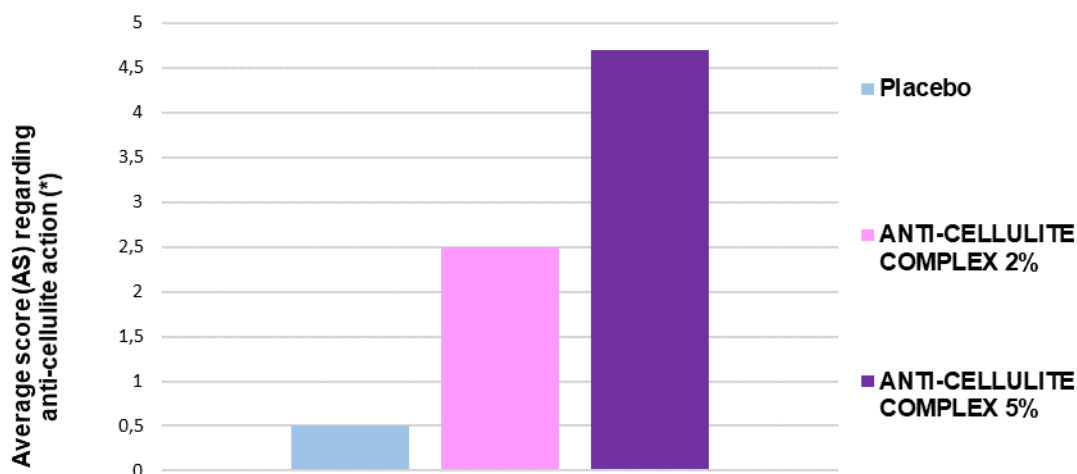
	Assay	N (volunteers)	Age (volunteers)	Placebo	ANTI-CELLULITE COMPLEX 2%	ANTI-CELLULITE COMPLEX 5%	Assay performed (Days)	Results measured (Days)
Anti-cellulite action	Double blind spot trial and subsequent cosmetic evaluation.	N = 30 25 ♀ and 5 ♂	25 – 48	Left side part	Right side part 15 volunteers.	Right side part. 15 volunteers.	D = 15	D' = 1



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SKIN CONDITION EVALUATION AFTER 30 DAYS



(*) Anti-cellulite action was determined by direct observation and measurement of nodules, orange peel appearance and swelling decrease of treated parts from volunteers (legs).

Total number of days in which the assay was performed (treatment was applied):
D = 15 days (every other day during the effectiveness test).

Total number of days in which the results were measured:
D' = 1 day (effectiveness test last day).

Average score:

Worst result: Zero limit value is assigned.

Best result: Five limit value is assigned.

Score is assigned to obtained results between the two limit values.

Average computation for each obtained results group is done:

Placebo, 2% ANTI-CELLULITE COMPLEX by BIOGRÜNDL, S.L., 5% ANTI-CELLULITE COMPLEX by BIOGRÜNDL, S.L..

Results meaning:

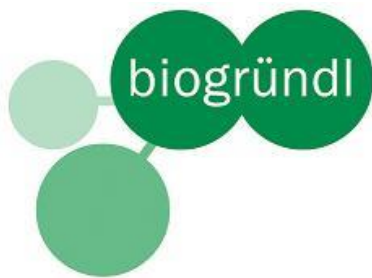
AS rank between 0 – 1: No significant changes.

AS rank between 1 – 2: Slight improvement regarding placebo.

AS rank between 2 – 3: Appreciable improvement regarding placebo.

AS rank between 3 – 4: Great improvement regarding placebo.

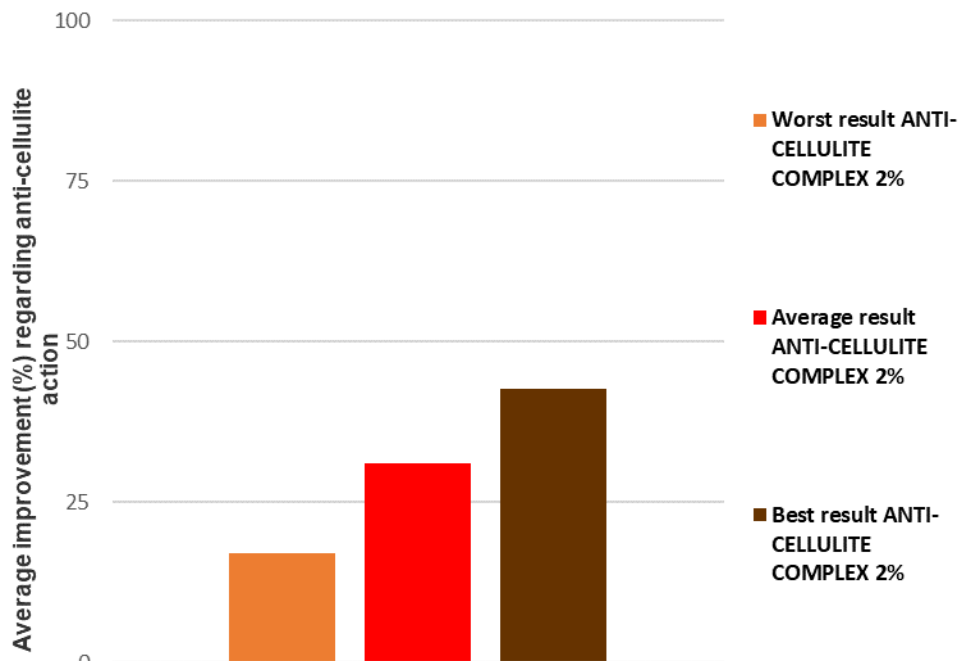
AS rank between 4 – 5: Excellent cosmetic result.



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ANTI-CELLULITE COMPLEX 2%

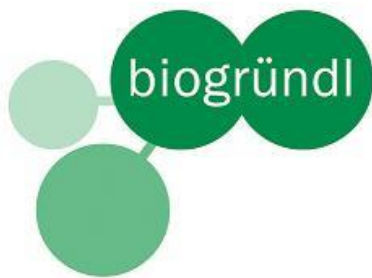


Results:

Worst result ANTI-CELLULITE COMPLEX 2%: **17%**.
Average result ANTI-CELLULITE COMPLEX 2%: **31%**.
Best result ANTI-CELLULITE COMPLEX 2%: **42,5%**.

Results meaning:

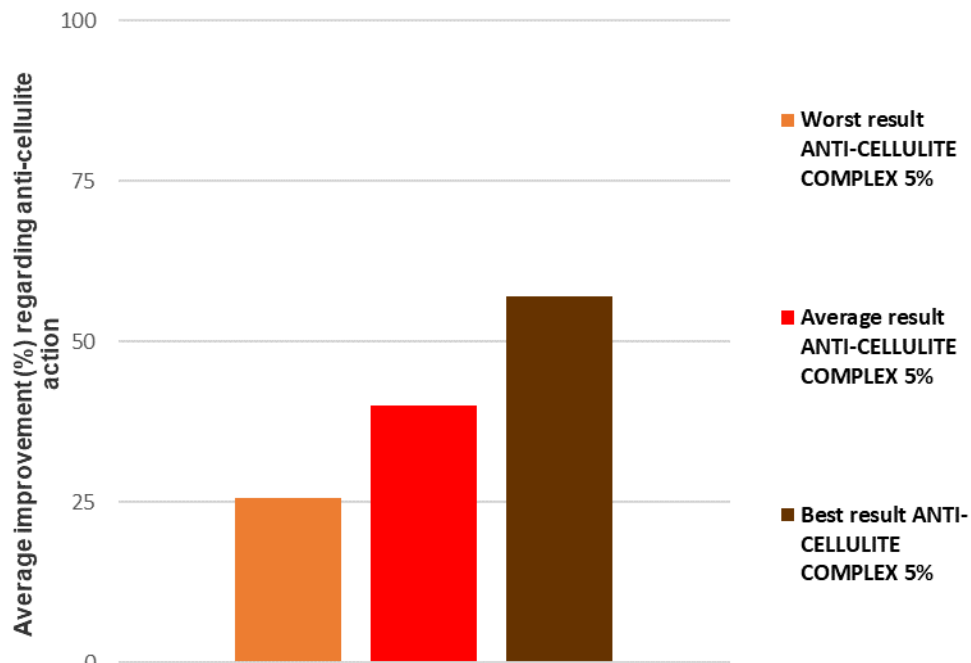
AI rank between < 20%: No significant changes.
AI rank between 21 – 40%: Slight improvement regarding placebo.
AI rank between 41 – 60%: Appreciable improvement regarding placebo.
AI rank between 61 – 80%: Great improvement regarding placebo.
AI rank between > 81%: Excellent cosmetic result.



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ANTI-CELLULITE COMPLEX 5%



Results:

Worst result ANTI-CELLULITE COMPLEX 5%: 25,5%.

Average result ANTI-CELLULITE COMPLEX 5%: 40%.

Best result ANTI-CELLULITE COMPLEX 5%: 57%.

Results meaning:

AI rank between < 20%: No significant changes.

AI rank between 21 – 40%: Slight improvement regarding placebo.

AI rank between 41 – 60%: Appreciable improvement regarding placebo.

AI rank between 61 – 80%: Great improvement regarding placebo.

AI rank between > 81%: Excellent cosmetic result.