VECTICELL LIPOLYSIS

synthos CARE

Cellulite involves changes in the dermis and subcutaneous tissue caused by the irregular proliferation of fat cells, the so-called adipocytes. Contrary to widespread opinion, this cosmetic and medical defect affects both women and men from various age groups. Cellulite, classified as a civilisation-related disease, is associated with lifestyle, diet and the use of different types of pharmaceutics.

Nowadays, there are many formulations, therapies and treatments on the market which promise instant results and the removal of the unwanted lesions. Low prices, inviting and easily available formulations, are often hardly effective, and act only superficially. On the other hand, treatments offered in beauty salons are expensive and invasive, which can be a serious barrier for many customers.

VECTICELL Lipolysis is a perfect alternative for the above-mentioned solutions. Inside the lipid bilayer vesicles of approx. 100 nm in diameter, three synergistically acting active ingredients are contained - L-carnitine, caffeine and sodium deoxycholate - which up to now have been used mainly in invasive aesthetic medicine treatments. These substances were selected in such a way as to most effectively reduce fat tissue, at the same time improving skin elasticity and firmness at the site of application, which have been proved in many studies.

L-carnitine speeds up the energetic metabolism of fatty acids and acts as a detoxificant for skin cells.

Sodium deoxycholate effectively liquefies the cell membranes of fat cells, the so-called adipocytes, allowing the release of the unnecessary products of metabolism (lipolysis)

Caffeine stimulates microcirculation, thus strengthening the action of the other active ingredients. Additionally, it speeds up lipolysis, leading to an increase in the blood level of glycerol and free fatty acids.

The action of **VECTICELL Lipolysis** was confirmed by numerous in-vitro and in-vivo studies which have been conducted in the past 2 years, using the latest-generation devices. The collected results demonstrated the beneficial action of the used active substances at the site of application, due to the high penetration into the deep skin layers which was confirmed for VECTICELL delivery system.

VECTICELL Lipolysis
Effects after use

- Improvement in skin structure
- Gradual reduction in cellulite and thigh diameter
- Stimulation of the fat-tissue-burning mechanism and reduction of its volume
- Improvement in skin firmness and elasticity
- Stimulation of the microcirculation
- Improvement in skin smoothness and softness

In vitro studies

Studies confirming an increase in the effectiveness of the action of caffeine and L-carnitine contained in the VECTICELL delivery system were conducted. The studies demonstrated an increase in the permeability, and a longer release of the substances, contained in it. The studies on VECTICELL Lipolysis confirmed a speed-up of fat hydrolysis in 3T3-L1 adipocyte cells and VECTICELL Lipolysis cytotoxic safety.

The permeability of VECTICELL Lipolysis

An examination on human skin with the use of Raman spectroscopy was conducted to visualise the depth to which VECTICELL Lipolysis penetrates. The studies showed that sodium deoxycholate contained in VECTICELL carrier penetrated the skin up to a depth of 2.5 mm +- 0.5 mm. Sodium deoxycholate in the free form remains on the epidermis or penetrates to a marginal degree.

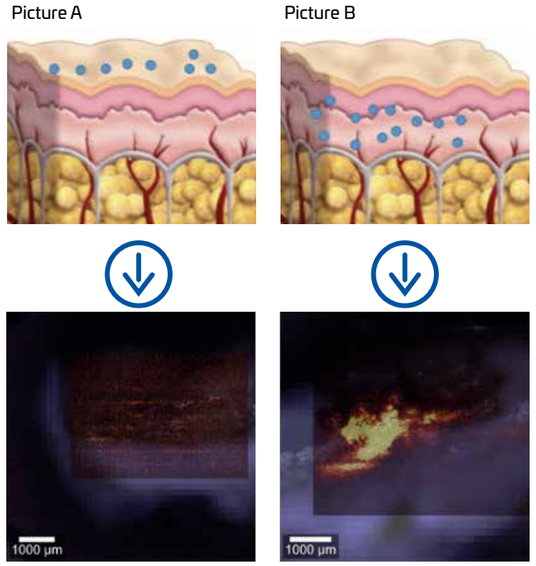
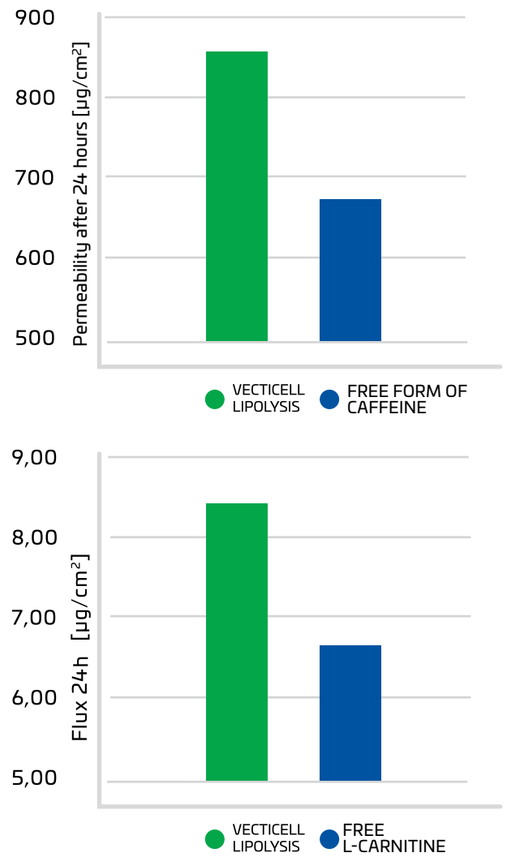


Figure 1: Permeability of sodium deoxycholate in free form (A) and in VECTICELL Lipolysis (B)

The permeability of caffeine and L-carnitine

A permeability test was performed with the use of Franz Cells chambers on a skin model on which VECTICELL Lipolysis solution, as well as a solution of free substances in the same concentration, were applied. Permeability was monitored after each hour, for 24 hours.

Figure 2: Permeability of caffeine and L-carnitine in the free forms and enclosed in the VECTICELL carrier

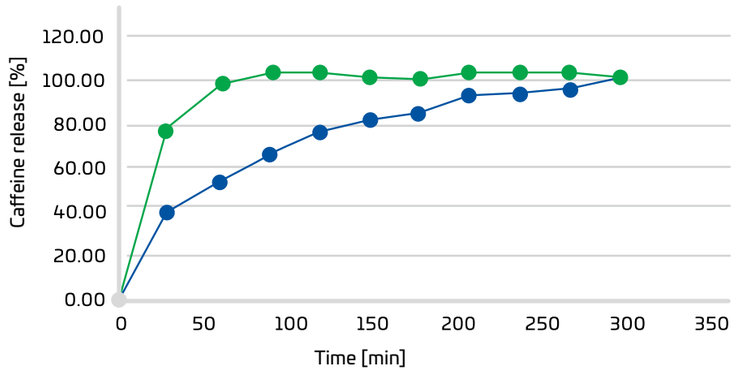


Results: The caffeine contained in the VECTICELL Lipolysis showed a 21% increase in permeability compared to the solution of the free substance. The increase in the permeability of the L-carnitine provided in VECTICELL Lipolysis was 22% more than free substance.

The release of caffeine and L-carnitine

A VECTICELL Lipolysis solution, and a solution of free substances of analogical caffeine and L-carnitine concentration, were dialysed into a PBS buffer of pH 7.4, and a change in substance release in time was observed. The measurements were conducted for 5 hours, and each time the concentration of the released substance was monitored using high-performance liquid chromatography.

Figure 3: Release of caffeine in the free form and enclosed in the VECTICELL Lipolysis.



Results: VECTICELL lipid bilayer significantly prolongs the process of caffeine release compared to its aqueous solution, which translates into an increase in the effectiveness of the action.

VECTICELL LIPOLYSIS

AN AQUEOUS SOLUTION OF CAFFEINE

The fusion of VECTICELL Lipolysis with cells

Investigating the fusion of the VECTICELL Lipolysis carrier with the in-vitro cells. In order to confirm the fusion of the VECTICELL Lipolysis with nHDF cells line in vitro. The carriers were fluorescently stained and incubated with the cells. After 1 hour, an image was taken using a fluorescent microscope.

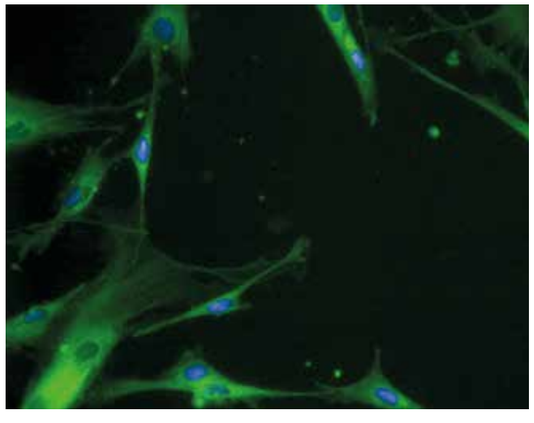


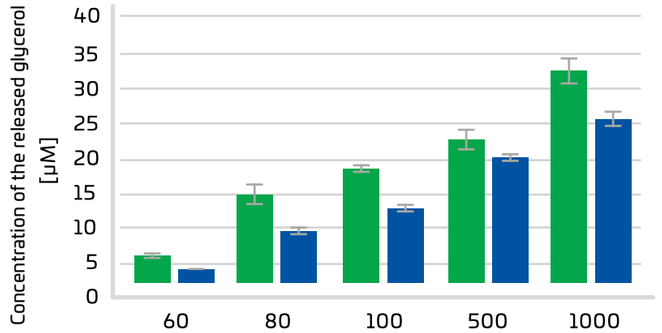
Figure 4: A photo of human fibroblasts under a fluorescent microscope

Results: Thanks to the use of high-quality phosphatidylcholine, the lipids contained in formed in-cell membranes, gradually releasing the active substances contained in the carrier. Additionally, thanks to the use of the carrier composed of phosphatidylcholine, sodium deoxycholate does not exhibit toxic properties, which was confirmed in a study of cytotoxicity applied to human fibroblasts in vitro. The mechanism of the action of deoxycholate contained in the carrier consists of building it into the cell membrane, and liquefying it, which in turn enables the effective release of fatty acids from the adipocytes. The above photo shows this process – the bright points are VECTICELL clusters, whereas the uniform colour is the content released from VECTICELL which has undergone fusion with the cells. The study using a fluorescent microscope proves the fact that VECTICELL provides active substances to the cells – this confirms the bioavailability of the active substances contained in this carrier.

The lipolytic activity of VECTICELL Lipolysis on adipocytes

Lipolytic activity testing was performed with the use of a 3T3-L1 adipocyte cell line, which was incubated with the analysed compounds, both in the free form and in the VECTICELL carrier. The active substance was applied to the cells in concentrations ranging from 600 to 1000 u µM. After 24 hours from the start of the test, the glycerol concentration was measured and its increase was proof of fat decomposition in adipocytes.

Figure 5: Glycerol concentration after 24 hours

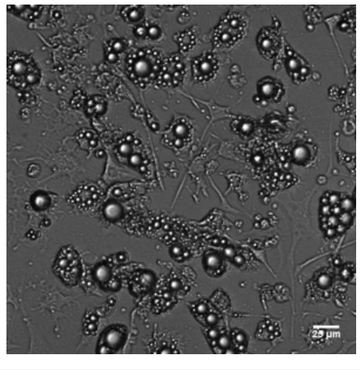


Results: The test showed that a tendency to fat hydrolysis in adipocytes is higher in the case of the administration of the substances encapsulated in VECTICELL Lipolysis than in the case of the administration of active substances in the free form. Microscopic images showing morphology confirm the disappearance of fat droplets inside the adipocytes.

VECTICELL LIPOLYSIS

ACTIVE SUBSTANCES IN THE FREE FORM

Picture A



Picture B

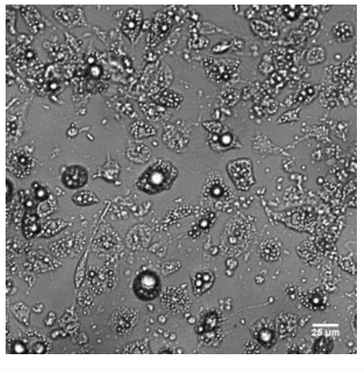
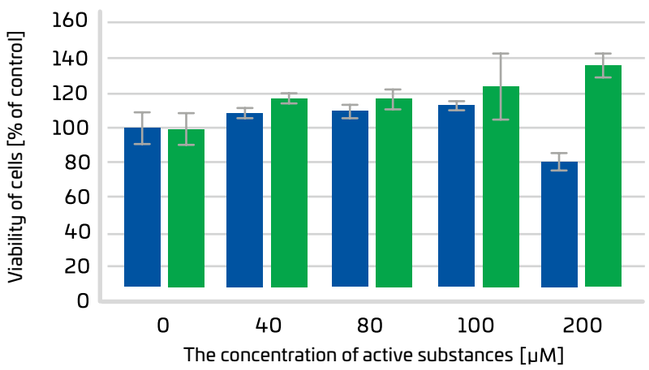


Figure 6: Adipocyte morphology before (A) and after (B) VECTICELL Lipolysis administration

The cytotoxicity of substances in the VECTICELL Lipolysis carrier and caffeine, L-carnitine, and sodium deoxycholate in the free form

Cytotoxicity testing was performed with the use of an MTS assay on an nHDF cell line. The culture was incubated for 48 hours in the case of the caffeine, L-carnitine and sodium deoxycholate encapsulated in the VECTICELL Lipolysis, whereas, at the same time, comparative measurements were performed with the use of a mixture of three active substances.

Figure 7: The substance cytotoxicity levels in relation to the cell lines



Results: The conducted tests did not reveal cytotoxicity. Together with an increase in VECTICELL Lipolysis concentration, a gradual increase in the proliferation of the fibrolast cells was noted. This test confirmed the toxicological safety of the formulation.

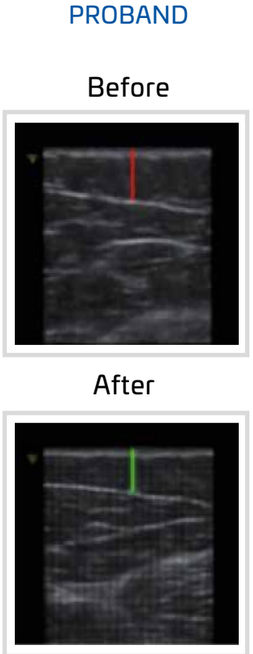
The in-vivo studies panel

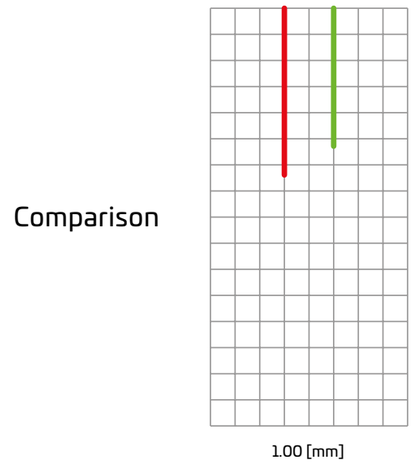
Thirty people who used a balm containing 5% VECTICELL Lipolysis for 6 weeks participated in the study. The balm was massaged into the skin on the thigh and left until absorbed. The action was repeated every day in the morning and in the evening, or more often if the skin required it. After 6 weeks, tests were conducted which proved the fact that the use of the balm with VECTICELL Lipolysis improved skin condition and had an anti-cellulite effect.

VECTICELL Lipolysis reduces the thickness of subcutaneous tissue

From a group of 30 probands, 10 persons were randomly selected, and the thickness of subcutaneous tissue was measured in them during ultrasound examination. In probands, on the skin on thigh a control area was determined, and the measurements were performed prior to the application of the formulation and after 6 weeks of using it.

Figure 8: Thickness of subcutaneous tissue



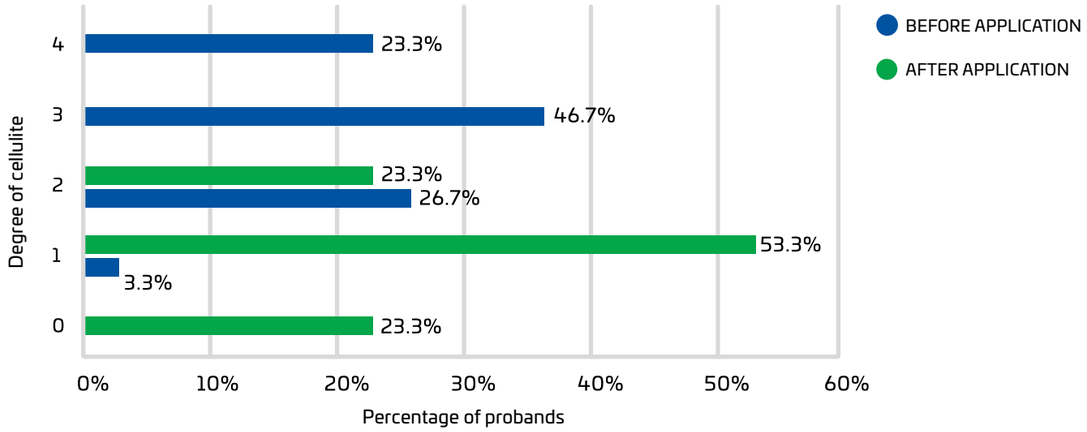


Results: The ultrasound examination revealed a reduction in fat-tissue thickness, on average by 6% after 6 weeks of using the formulation. The active ingredients contained in the VECTICELL Lipolysis support the reduction in the subcutaneous fat tissue – they decrease its volume and thickness, thus contributing to its becoming thinner and to the improvement in the whole-body silhouette.

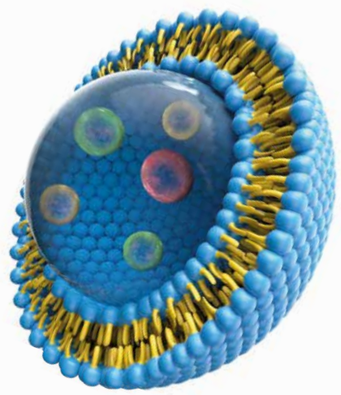
VECTICELL Lipolysis reduces the cellulite degree

The conducted study involved a comparison of the areas of the probands' skin affected with cellulite before and after the application of 5% VECTICELL Lipolysis balm. The aim of the study was to compare the degree of reduction and improvement in skin appearance which had been evaluated on 0-4 scale prior to the study, where 0 meant a lack of symptoms and 4 corresponded to a significant degree of cellulite.

Figure 9: Reduction of the cellulite level



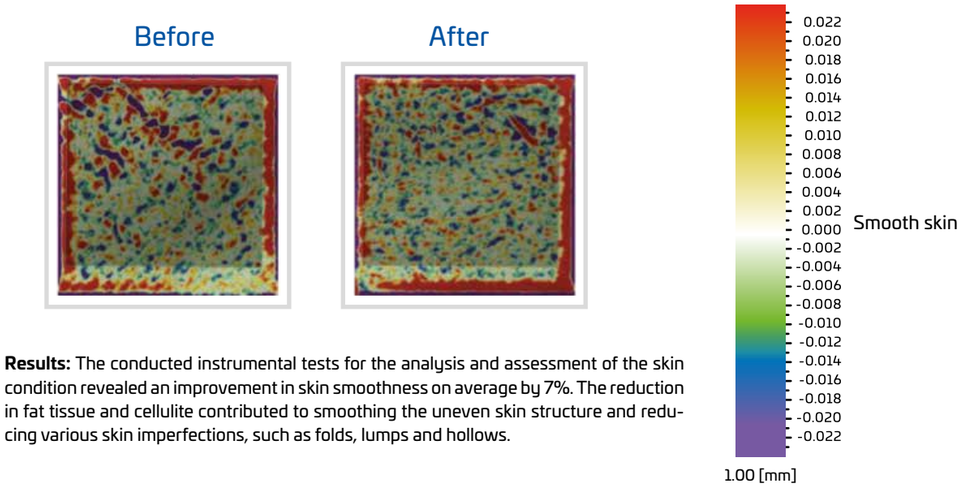
Results: A thermographic examination (CelluMeter) revealed the complete disappearance of 3- and 4-stage cellulite after the application of the balm containing 5% VECTICELL Lipolysis. However, in 23% of the studied participants a complete reduction in cellulite was observed.



VECTICELL Lipolysis smoothens the skin

The control areas on the probands' thighs were determined. The measurements were taken before the commencement of the application of the formulation, and after 6 weeks of the application.

Figure 10: Skin smoothness



Results: The conducted instrumental tests for the analysis and assessment of the skin condition revealed an improvement in skin smoothness on average by 7%. The reduction in fat tissue and cellulite contributed to smoothing the uneven skin structure and reducing various skin imperfections, such as folds, lumps and hollows.

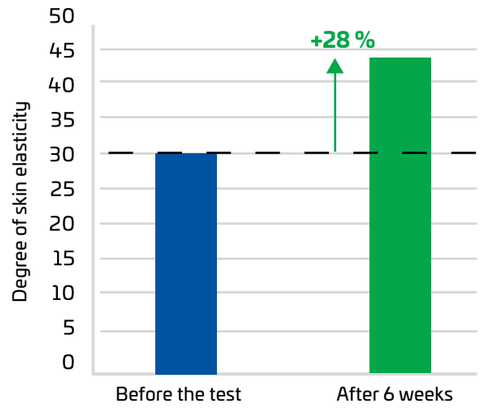
VECTICELL Lipolysis smoothens the skin

Test:

In the probands, on the thigh skin, two areas of 1 cm x 1 cm each were determined, and the measurements were performed prior to the application of the formulation, and after 6 weeks of using it.

Results: The instrumental tests revealed an improvement in skin elasticity on average by 28% after 6 weeks of application.

Figure 11: Skin elasticity



Summary

VECTICELL Lipolysis is an innovative product enabling the creation of a cosmetic which, if applied systematically, will effectively eliminate all vestiges of cellulite. Thanks to its unique composition, it has a very-beneficial effect on both the appearance and condition of skin affected with cellulite and excess fat tissue. Probands' opinions confirm that regular, intense, massaging in of a cosmetic containing VECTICELL Lipolysis into the skin contributes to the effective reduction of cellulite symptoms which have persisted for a long time. Active ingredients contained in VECTICELL Lipolysis support the reduction of subcutaneous fat tissue - they decrease its volume and thickness, thus contributing to their becoming thinner and to an improvement in the whole body silhouette.

Product description

Viscous, opalescent solution.

Appearance

Opalescent solution of milky to yellow-milky colour

INCI

Aqua/Water, Phosphatidylcholine, Carnitine HCl, Propylene Glycol, Caffeine, Sodium Deoxycholate, Cholesterol, Xanthan Gum, Dehydroacetic Acid, Benzyl Alcohol.

Storage conditions

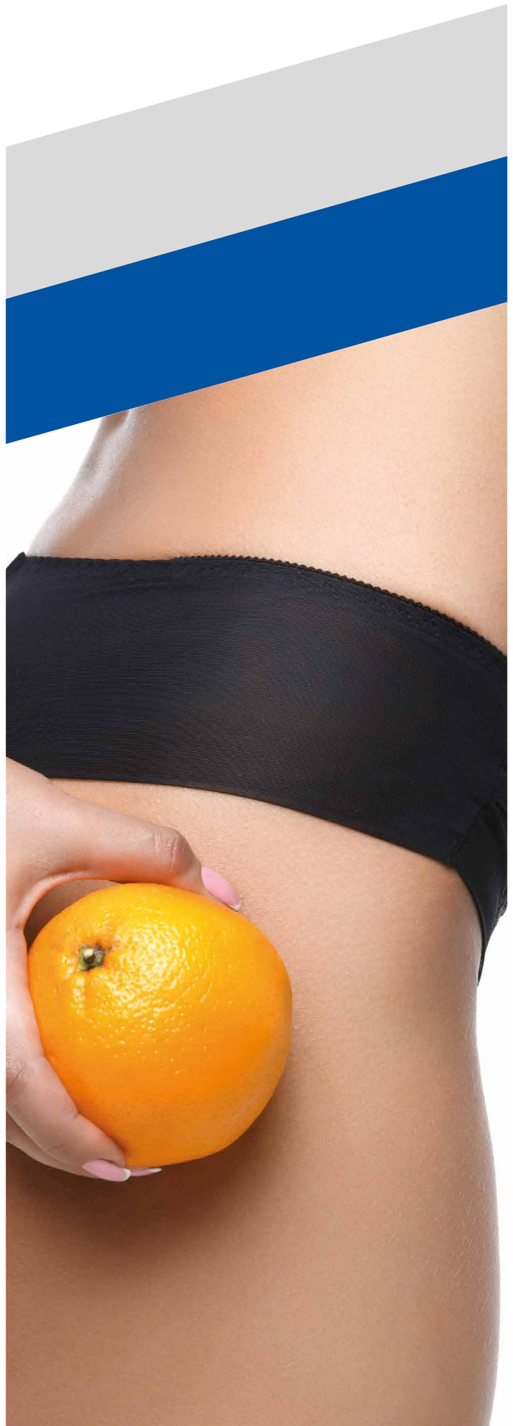
Store the product in its original packaging. Keep the product in a sheltered place, protected from direct sunlight, at temperature of up to 20 ± 5°C.

Shelf life

12 months from the production date.

Recommended formulation conditions

Shake the product before each use.
It is recommended to add it to the final product at the final stage of production,
at a temperature of up to 35°C.
The optimal pH of the formulation during the addition of the raw material
4.0 - 7.0. Alkaline pH is not recommended.
Water soluble.
Recommended concentration 3% – 5%.



Life Science Park, Cracow

VECTICELL

delivery system

Synthos CARE
Synthos Dwory 2
Spółka z ograniczoną
odpowiedzialnością
Spółka komandytowa

ul. Chemików 1, 32-600
Oświęcim, POLAND

Customer Support Centre
Tel. +48 33 847 42 47
Fax. +48 33 847 42 47

Sales Department
+48 885 800 398

care@synthosgroup.com
www.synthoscare.com