

KitoZyme



KiOnutrime-CsG[®]

The proven weight management tool

A proven weight management tool

KiOnutrime-CsG[®] is a natural ingredient that is scientifically proven to help people to manage their weight. In a recently completed clinical trial¹ it was found that overweight subjects consuming KiOnutrime-CsG[®] lost an average of 3.2kg over three months, compared with a small weight increase on average in the control group.

Produced by KitoZyme at its manufacturing facility in Belgium, KiOnutrime-CsG[®] works by safely preventing some of the fat in food from being absorbed by the body. It is a cationic (positively charged) biopolymer that binds with anionic (negatively charged) molecules such as fats and fatty acids, and obstructs the emulsification and absorption of cholesterol. Taken just a few minutes before a meal, KiOnutrime-CsG[®] will bind dietary fat in the stomach to form a gel that is later excreted naturally without being absorbed.

A previous study carried out using a lab-based model of the human gut showed that KiOnutrime-CsG[®] can bind 42% of the fats ingested in a typical meal², as shown below in Figure 1. The latest human study, which is awaiting publication in a peer-reviewed journal, confirms that this mechanism has a statistically significant impact on weight loss in healthy overweight people.

Percentage of lipids bound by KiOnutrime-CsG[®]

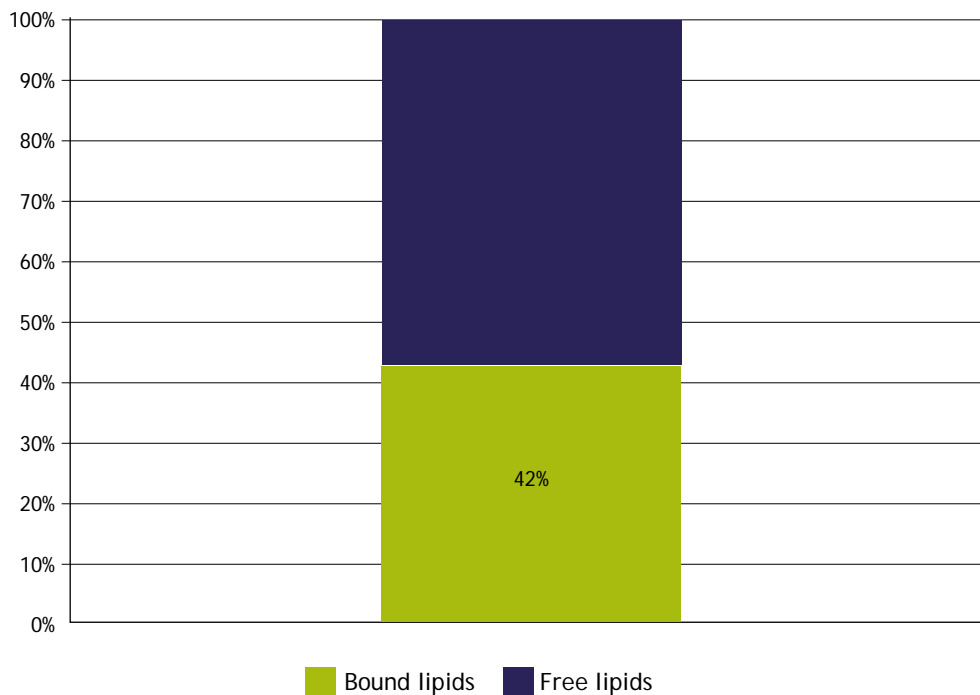


Figure 1. A lab-based study demonstrated that KiOnutrime-CsG[®] binds 42% of dietary fats ingested during a typical meal²

Addressing the obesity crisis

With obesity remaining a major public health challenge around the world, the market potential for KiOnutrime-CsG® is huge.

The World Health Organization (WHO) reported last year that more than 1.9 billion adults aged 18 and over were overweight, and 600 million of these were obese³. WHO also noted that these numbers are continuing to rise, with worldwide obesity more than doubling since 1980.

Obesity is defined as having a body mass index (BMI) of at least 30. It is associated with a significant increase in the risk of chronic illnesses such as cardiovascular disease, diabetes and some types of cancer. Meanwhile, the global weight loss and weight management market is forecast to reach a value of \$206.4 billion by 2019, up from \$148.1 billion in 2014, representing a compound annual growth rate of 6.9%⁴.

In this context, it is clear there has never been a better time for nutrition companies to create effective products that can contribute to the fight against obesity. Clinical research shows that KiOnutrime-CsG® is the perfect ingredient to help them achieve this.

To demonstrate the benefits of KiOnutrime-CsG® in human subjects, KitoZyme commissioned a multi-centre, single-blind clinical trial. The research took place at four different hospitals and medical research centres between late 2014 and early 2015. Healthy overweight men and women aged between 18 and 65 were divided into two groups: a treatment group and a control group taking a placebo. Apart from being overweight with a BMI between 26 and 35 at the start of the trial, none of those taking part were suffering from any serious health conditions or were pregnant.

The 64 people in the treatment group were given five capsules per day, each containing 500mg of KiOnutrime-CsG®. They took one capsule in the morning, two 15 minutes before lunch and two more 15 minutes before dinner. The 32 people enrolled in the control group followed the same procedure but their capsules contained a placebo. Besides these requirements, everyone continued with their regular diet and exercise patterns and all the participants kept a diary to record their experiences and encourage compliance. Out of 96 people enrolled, a total of 86 people completed the study.

The researchers observed a statistically significant gradual reduction in bodyweight in the treatment group throughout the study, compared with a baseline measured at the start. In contrast, there was no statistically significant change in the body weight of the group who received the placebo.

Overall, the subjects in the treatment group lost 3.2kg of their body weight on average over 90 days, compared with the baseline (see Figure 2, overleaf). The researchers also observed statistically significant reductions in average body fat, as well as in the upper abdominal, hip and waist circumference of people consuming KiOnutrime-CsG®.

As well as the primary goal of measuring the impact of KiOnutrime-CsG® on weight loss, the study also evaluated body fat, muscle mass, bone mass, BMI and visceral fat. Subjects treated with KiOnutrime-CsG® showed a statistically significant reduction in all these parameters over the course of the trial, while there was no significant change within the control group.

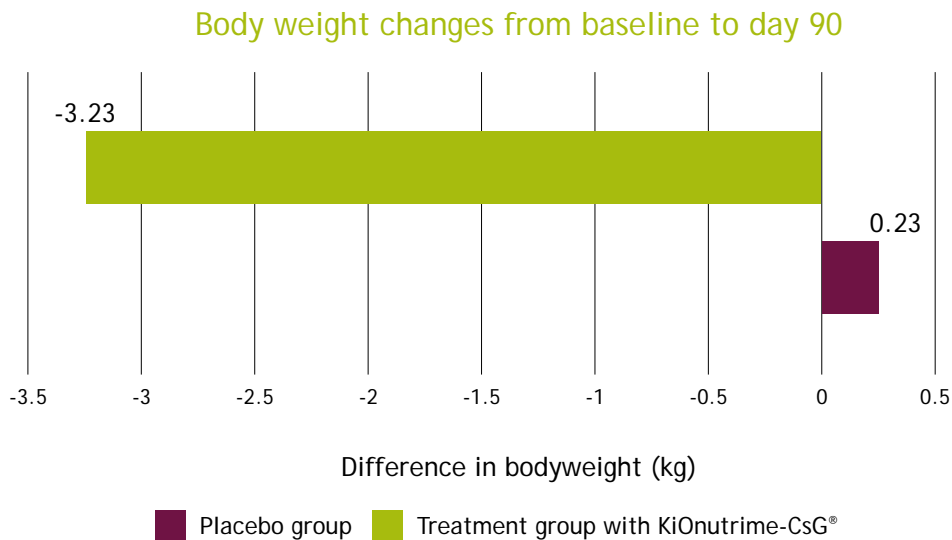


Figure 2. In a new clinical study conducted in 2015, the body weight of overweight subjects consuming KiOnutrime-CsG® decreased on average by 3.2 kg

As well as having an impact on serious health conditions, obesity can have a long-term detrimental effect on people's sense of wellbeing, so it is worth noting that the people treated with KiOnutrime-CsG® actually felt better at the end of the study.

The researchers used a standard questionnaire to check various aspects of their physical and mental wellbeing. Subjects in the treatment group reported an improvement in their overall quality of life over the 90 days of the trial, with a boost in physical wellbeing being the main benefit recorded.

Safety is paramount when testing any potential treatment and the researchers in the KiOnutrime-CsG® trial concluded that the product was safe and well tolerated.

Commercial opportunities

KiOnutrime-CsG® is an animal-free chitosan that is completely odourless and tasteless, making it suitable for a range of applications. It dissolves in just 10 minutes in the acidic environment of the stomach. This means that a dose can be administered almost immediately before a meal, making it convenient and easy for consumers to remember to take. Most other fat binding agents need to be taken up to 30 minutes before a meal, which makes compliance more difficult.

KiOnutrime-CsG® is available as an ingredient for dietary supplements in the USA, where the ingredient has GRAS status. In the European Union, KiOnutrime-CsG® is available from KitoZyme in finished products that are classified as medical devices. KitoZyme offers a range of complete, over-the-counter solutions that are ready to be marketed as own-label or branded products. These include tablets, capsules and sticks. KiOnutrime-CsG® is considered safe under the EU's Novel Foods regulation and is already approved by the European Food Safety Authority (EFSA) to carry the health claim that it maintains normal blood LDL cholesterol at a dose of 3g per day.



Chitosan is a biopolymer traditionally extracted from the shells of crustaceans. However, KitoZyme has developed a unique and patented process to derive it from the cell walls of a non-genetically modified fungus called *Aspergillus niger*. Not only does this make it suitable for vegetarians and vegans but it is also Halal and Kosher-certified.

KitoZyme is already the leader in the weight management sector in Switzerland and is a major presence in France, Spain, the UK, Belgium, Thailand and Taiwan. The company started life in 2000 as a spin-off from the University of Liège. For the first 10 years, it focused on research and development, scaling up its patented biopolymer production processes and securing regulatory approvals. Today, KitoZyme operates a modern full-scale biopolymer manufacturing facility in Liège-Herstal in Belgium.

KitoZyme works with a network of international partners and distributors, some of which are household names in their home markets. Now it is looking to expand its international activities and achieve even stronger growth for itself and its customers. Innovation is key to this strategy and, with KitoZyme launching several new products a year based on its patented technologies, the company offers a steady stream of exciting opportunities.

KiOnutrime-CsG[®] at a glance

- Reduces body weight by 3.2kg on average over three months
- Binds up to 42% of dietary fats
- Animal-free – suitable for vegetarians and vegans
- Non-allergenic
- Generally recognized as safe (GRAS) in the USA
- Positive EFSA opinion related to maintaining LDL-cholesterol
- Available as products approved as medical devices in Europe
- Odourless and colourless
- Kosher and Halal
- Dose: up to 3g per day
- Convenient to take just before a meal

For more information:

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References

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3. <http://www.who.int/mediacentre/factsheets/fs311/en/>
4. <http://www.prnewswire.com/news-releases/global-weight-loss-and-weight-management-market-2015-2019---fitness-equipment-surgical-diet--weight-loss-services-analysis-300071062.html>