

Spiralin®

Ocean Pharma GmbH, Reinbek



Facts on the Project

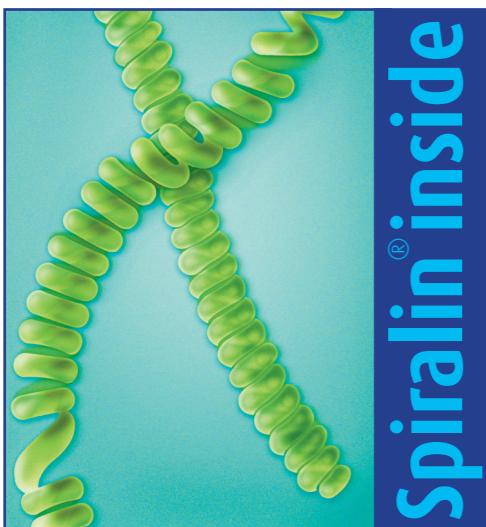
The name of the active ingredient Spiralin® originates from the micro algae species Spirulina. Due to its extraordinary nutritional value it is already well known to many. There are lots of Spirulina powder and tablets offered as supplements. However, Spiralin® has little to do with that.

As a participant in large university research projects Ocean Pharma has systematically screened hundreds of micro algae strains not with regard to their nutritional value but in respect of antimicrobial activities. The Spirulina micro algae with an age of unbelievable 3.6 billion years belongs to the earth's oldest life forms which developed effective self-protection mechanisms against fungi, bacteria and viruses during the evolutionary process. This had been very successful, otherwise it would no longer exist. But only a few tested resources satisfy the minimum requirements for the activity level defined by Ocean Pharma. The selected strains are added as gross mass to a patented activating process since the antimicrobial activities

only develop their full potential under a stress load. In an additional process step they are standardized in a solution.

The result is Spiralin® with a unique efficacy profile, which includes not only all known human pathogenic fungi but also problematic germs such as Staph. aureus, and even its antibiotic-resistant variants (MRSA). As shown in experimental studies with a research team from the German Center for Infection Research as well as a clinical study under the direction of Prof. Dr. med. Kristian Reich (Dermatologikum Hamburg), the antiviral effects of Spiralin® are based on a polysaccharide called Calcium-Spirulan which prevents the viruses (et.al. HSV 1, HHV-8) from penetrating the cell membrane of healthy cells thus interrupting the viral circle.

Ocean Pharma is an owner-led company from Reinbek near Hamburg. Founded in 1978 it focuses on natural active ingredients. Since approx. 10 years the research and development activities concentrate on microalgae with particular antimicrobial characteristics.



Spiralin – Active Ingredient of the Year 2015 in aesthetic dermatology

Interview with K. Reich, Hamburg



Nature offers a vast range of solutions for our health problems. This has been known for thousands of years. Because of the almost infinite variety, the mysteries can only be unlocked step by step. From the editor's perspective such a step has now been taken with the specially processed microalgae extract Spiralin®. A new scientific study published in the Journal of Allergy and Clinical Immunology, one of America's leading professional journals, records strong anti-viral protective effects of the microalgae extract Spiralin®. In a clinical trial (PROTECT study) it even proved superior to the market-leading pharmaceutical topical product against herpes labialis. We talked about the results with the clinical leader of the PROTECT study, Prof. Dr. med. Kristian Reich of the Dermatologikum Hamburg.

Aesthetic dermatology:

Prof. Reich, could you please briefly describe how the PROTECT study was designed and what are the main results?

Prof. Reich:

Firstly, one should say that the scientific work consisted of two parts. On the one hand it was shown in extensive laboratory experiments that the microalgae extract, and particularly a polysaccharide contained therein, protects human keratinocytes from a herpes simplex infection by inhibiting the attachment of the virus to the cell, the first step of the infectious process. Keratinocytes are the natural host cells for herpes virus. We were able to develop a cream containing not only the microalgae extract but also the protective polysaccharide in a special formulation. In a true bench-to-bedside approach we aimed to clinically test the protective effects of this formulation against herpes labialis.

This was the second part of the work, the so-called PROTECT study, which investigated herpes prophylactic effects

in a population of high-risk individuals, namely women with a history of herpes labialis who were about to receive a permanent make-up procedure (PMU). This patient population was selected based on the fact that PMU is a strong trigger factor of herpes labialis in susceptible patients due to the invasive pigment enhancement of the lip contour. Which is the reason why professional cosmetic institutes offering the procedure normally recommend a prophylactic therapy with either an antiviral cream or even a systemic antiviral medication. Therefore, the PMU procedure is particularly suited to serve as a clinical model for the induction of lip herpes and to investigate the prophylactic effects of the new cream.

The PROTECT study analysed the data from 198 female volunteers with recurrent herpes labialis undergoing the PMU procedure. The volunteers were divided into 3 groups: group 1 received prophylactic treatment with a lip cream containing the active ingredient acyclovir, group 2 received tablets

containing acyclovir or valacyclovir, and group 3 received the Spirularin® HS cream from Ocean Pharma containing the active ingredient Spiralin®. The results can be summarized as follows: as expected the systemic antiviral drugs showed the strongest prophylactic effects. Remarkably however, among the topical therapies, the lip cream with the micro-algae active ingredient Spiralin® showed a significantly better protective effect compared to the acyclovir containing cream. With regard to crust formation, a frequent and bothersome problem during herpes labialis, the Spiralin® containing lip cream was superior not only to the acyclovir cream but even the antiviral tablets. While every second participant in the Spiralin® group did not develop crusts on the lips, 88 % of those receiving the acyclovir containing cream group and 83 % of individuals treated with antiviral tablets did. The fact, that the participants in the Spirularin® HS group rated the moisturizing effects better than participants in the two other groups is probably best explained by the additional nourishing effects of the special formulation of the Ocean Pharma product.

Aesthetic dermatology:
What explanation do you have for the lower encrustation rate of a micro algae substance? After all, Acyclovir is a pharmaceutical active ingredient.

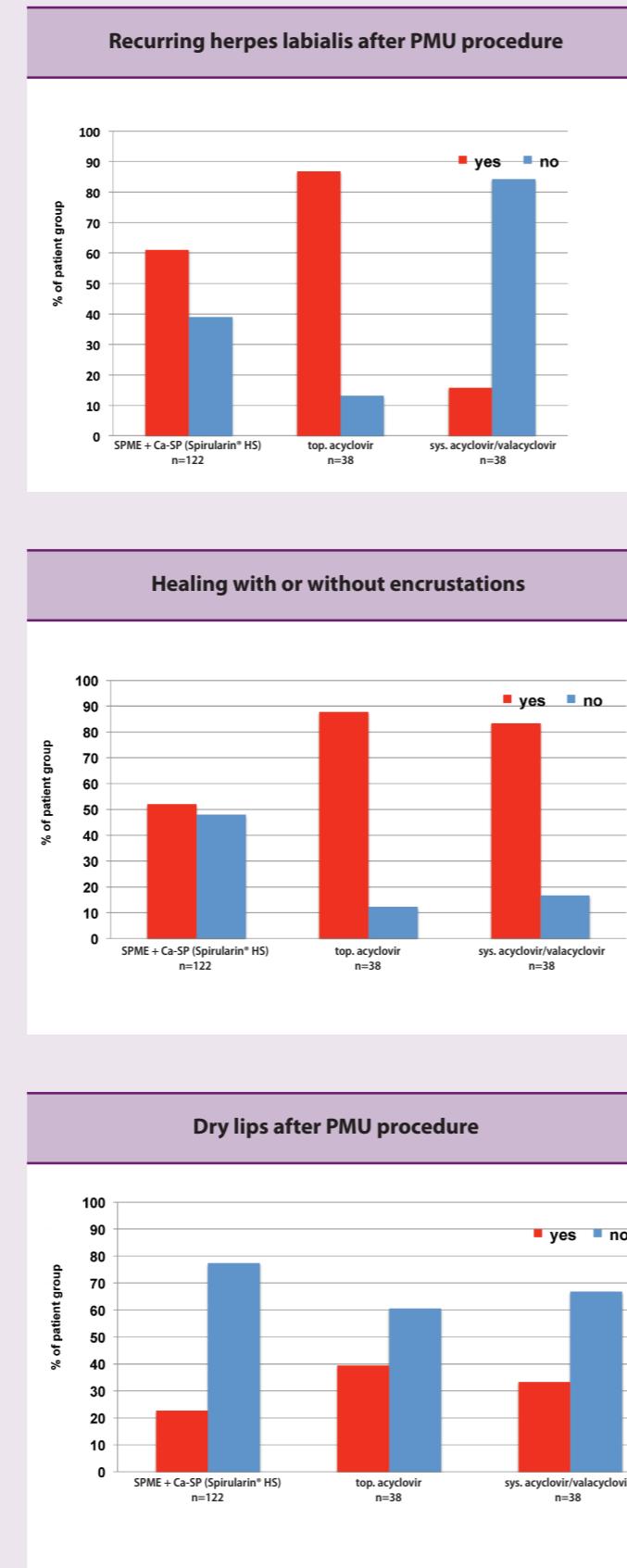
Prof. Reich:

My explanation for the low rate of crust formation with the new cream is as follows: crust formation on the lips is the consequence of inflammation and cell damage caused by the viral infection and probably a secondary bacterial infection frequently related to *Staphylococcus aureus*. Laboratory tests have not only shown strong antiviral effects of Spiralin® but also regenerative and antibacterial effects, particularly against *Staphylococcus aureus*. It may therefore be speculated that these additional activities contribute to the strong reduction of this often very annoying manifestation of lip herpes.

Aesthetic dermatology:
That sounds very impressive. Are the results given in the study statistically significant?

Prof. Reich:

Yes, the results are statistically significant.



III. 1a – c: Results of the clinical PROTECT study.

Aesthetic dermatology:
From your point of view, how should the Spirularin® HS cream be used?

Prof. Reich:

The results discussed above along with the fact that Spirularin® HS cream can be used safely every day, create new opportunities in the prophylaxis of recurrent herpes labialis. With previous antiviral therapies it is important to recognise early symptoms of a herpes labialis and to commence the treatment just at the right moment in order to achieve a faster healing and a less severe course of the flare. With Spirularin® HS there is now a lip care product with herpes protective effects available, which can principally be applied on a daily basis.

This is particularly true for patients with frequent exacerbations of lip herpes, who may want to use the invisible care as their daily lip care. The lip cream can also be applied as prophylactic regime only during sensitive time periods, i.e. before and during events that usually lead to lip herpes exacerbation in a given individual. Many people know what will trigger their lip herpes, for example situations with emotional stress or intensive sun exposure. This permits a more targeted intervention to prevent outbreak of herpes labialis for a limited period of time, e.g. during exams or before and during a ski holiday or a sailing trip.

Aesthetic dermatology:
Why is it that a micro-algae can have such protective effects?

Prof. Reich:

The Spirulina micro-algae already exist on this planet for billions of years. In their natural environment, e.g. in tropical seas, they are exposed to numerous potential pathogens and can be infected by viruses and bacteria. The algae have developed simple but effective defence mechanisms and we believe that the Spiralin® extract contains at least some of them as exemplified by the presence of a sugar with antiviral activity. The principle to try to use protective

molecules from simple species is not new. Remember that one our basic antibiotics, penicillin, has originally been isolated from moulds.

Aesthetic dermatology:

Do all the Spirulina micro algae have these effects?

Prof. Reich:

The answer is a definite no. Only certain strains of *Spirulina platensis* which are grown and purified under specific conditions show the anti-microbial activity. The patent-protected extraction process is needed to generate and maintain the active ingredients. It should also be clear that Spirulina as a dietary supplement, which is familiar to many people due to its high content of important nutrients, will not have these anti-viral or anti-bacterial effects as the active ingredients are destroyed during digestion.

Aesthetic dermatology:

Where do you see further fields of application for the micro algae extract Spiralin®?

Prof. Reich:

Products with these ingredients are so-called cosmeceuticals, i.e. cosmetic products with the additional value of an active ingredient. This is particularly true for products containing the micro-algae extract such as the Spirularin® HS cream for the lips, which require a complex extraction and standardization process. As herpes also affects the genital area and may even lead to dangerous infections of the cornea of the eye, it would be desirable to further test and develop such cosmeceuticals for the treatment of these regions, for example, in case of the latter, in the form of Spiralin® containing eye drops.

Aesthetic dermatology:

Prof. Reich, many thanks for this interview.