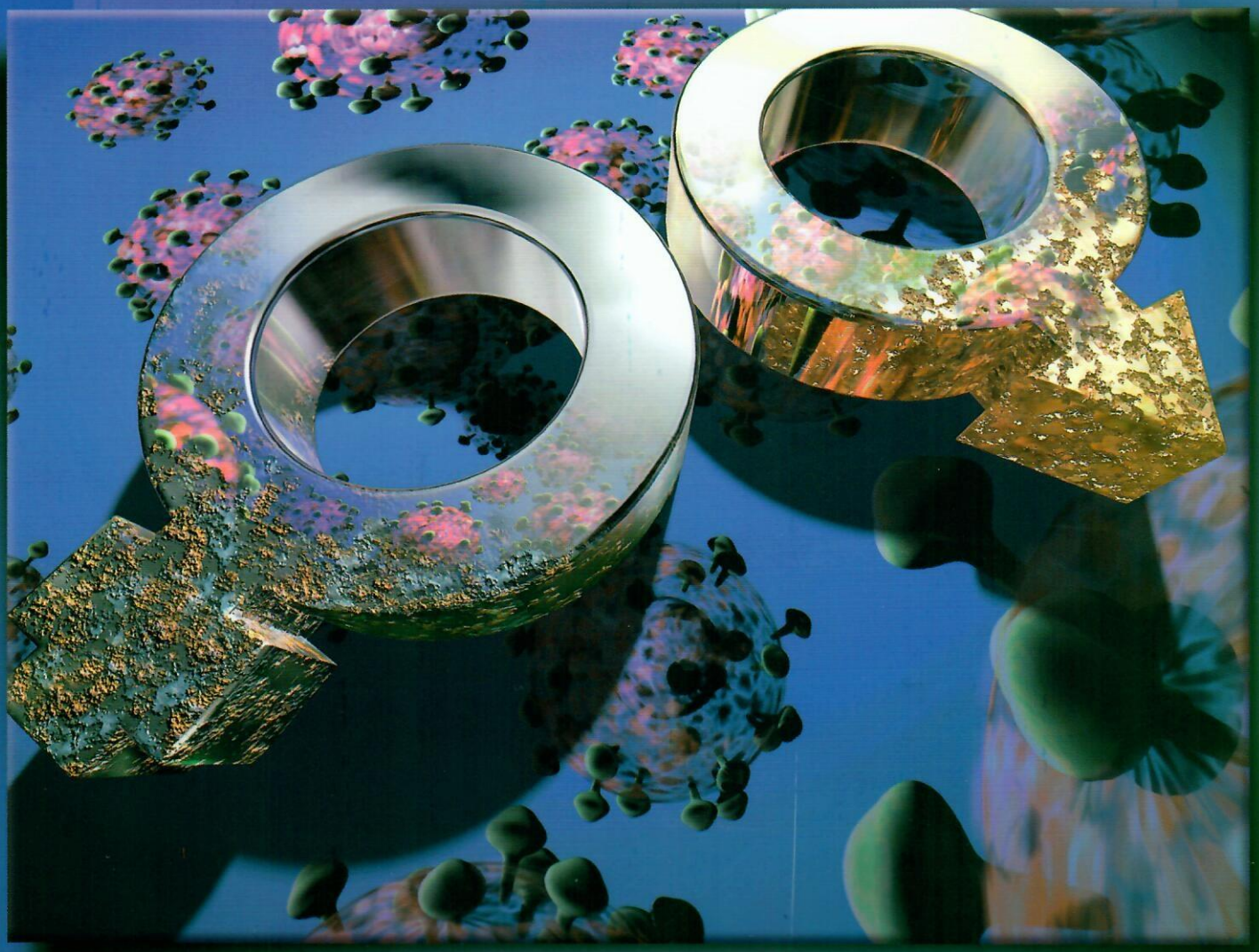


PROPHYLAXIS AND TREATMENT OF VULVAR AND CERVICAL INTRAEPITHELIAL NEOPLASIA (VIN AND CIN), HUMAN PAPILLOMAVIRUS, HERPES VIRUS, AND OTHER SEXUALLY TRANSMITTED DISEASES

catalysis

catalysis

Comprometidos con la Salud

Catalysis, S.L. was born as a private and independent company that dedicates its efforts to research and the development of products in the pharmaceutical, cosmetic, and dietary fields.

OUR MAIN ACTIVITY IS RESEARCH

A team of scientists works at the search of new remedies to relieve the suffering caused by widespread diseases such as psoriasis, diabetes, asthma, osteoporosis, arthritis, genital and oral herpes, immunodepression (AIDS), cancer, tuberculosis, hepatitis, etc.

The aim of our research is to discover treatments without the use of aggressive medicines that, all too often, produce terrible side effects.

Our products are harmless and based on the latest discoveries of the beneficial effects that ANTIOXIDANTS have on FREE RADICALS in our organism.

Manufactured by pharmaceutical laboratories equipped with the most advanced technologies, our products undergo the most rigorous controls that the European Union imposes by law on all the manufacturers of pharmaceutical, cosmetic, and dietary products that operate within its frontiers.

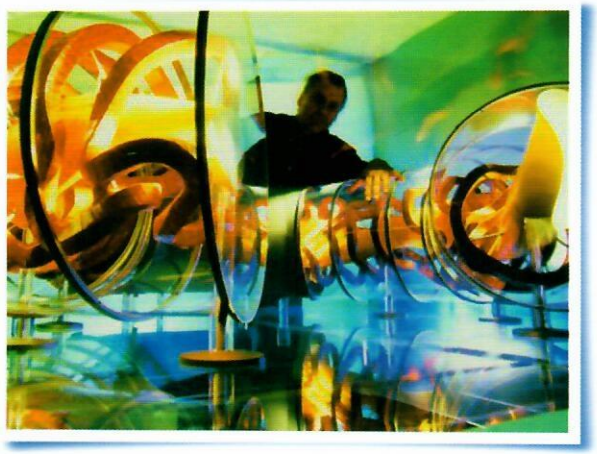
DISTRIBUTION THROUGHOUT THE WORLD

- **Europe**
  Albania, Belarus, Croatia, Cyprus, Czech Republic, Estonia, France, Hungary, Latvia, Lithuania, Moldavia, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Turkey, United Kingdom, and Ukraine.
- **America**
  Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, USA, and Venezuela.
- **Africa**
  Algeria, Botswana, Egypt, Ghana, Ivory Coast, Kenya, Lesotho, Malawi, Nigeria, Sierra Leone, South Africa, and Tanzania.

- **Middle East**
  Bahrain, Jordan, Kuwait, Lebanon, Qatar, Saudi Arabia, and United Arab Emirates (U.A.E.).
- **Asia**
  Armenia, Azerbaijan, Bangladesh, China, Georgia, Indonesia, Japan, Kazakhstan, Kyrgyzstan, Malaysia, South Korea, Taiwan, Thailand, Turkmenistan, Uzbekistan, and Vietnam.

Our secret?

Molecular activation



The biocatalytic process of MOLECULAR ACTIVATION considerably improves the biological activity and the biochemical reactivity of all antioxidant molecules.

This method of MOLECULAR ACTIVATION is much more effective when applied to a far wider range of hydrosoluble and liposoluble molecules.

We know the answer to this ACTIVATION in numerous antioxidants of all kinds and also the mechanism by which the accumulated electrons are able to reduce the free radicals of oxidant molecules.

In this mechanism, we have observed greater synergy between some antioxidants used that are sometimes capable of considerably increasing their overall antioxidant capacity.

Many factors can influence the ACTIVATION of all antioxidants.

Amongst the most important chemical factors are the molecular structure, the active functional groups, specific antioxidant catalysts, the molecular weight, the pH, double carbon bonds, their solubility coefficient, etc., as well as the antioxidant capacity of each molecule.

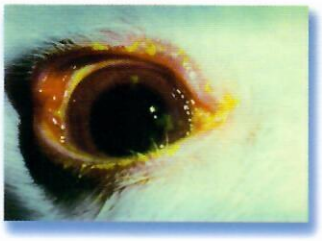
The duration and the intensity of MOLECULAR ACTIVATION are amongst the most influential and important physical factors.

Not all antioxidants require the same ACTIVATION time to reach their maximum antioxidant capacity. The most important parameter for the control of better performance is their optimization. Once their highest antioxidant capacity is at its most favourable peak, ACTIVATION must be suspended because, after that maximum peak, their antioxidant capacity normally starts to diminish gradually or quickly.

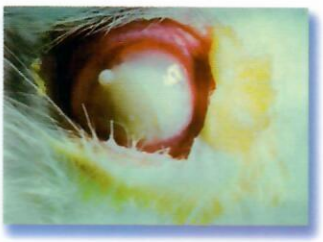
When there is a mixture of two or more antioxidants, the optimal ACTIVATION time is previously calculated for each preparation separately, and this fixed parameter is always respected.

Bioassay on rabbit cornea

Vilas P. et al. (1989): Antiviral activity of a D-glucosamine derivate against herpetic ulcers (HSV type 2) in rabbit cornea. Acta ophthalmologica 67:55-60.

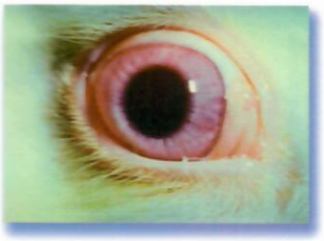


Control of HSV-2 virus
with non-activated glucosamine
4 days after viral infection



Control of HSV-2 virus
with non-activated glucosamine
14 days after viral infection

Treatment of HSV-2 virus
with activated glucosamine
4 days after viral infection



Treatment of HSV-2 virus
with activated glucosamine
14 days after viral infection

Treatment of HSV-2 virus
with acyclovir
4 days after viral infection

Treatment of HSV-2 virus
with acyclovir
14 days after viral infection

These results demonstrate that MOLECULAR ACTIVATION is essential and necessary to increase biological activity and obtain this way the greatest effectiveness in the treatment of diseases which directly or indirectly produce free radicals.

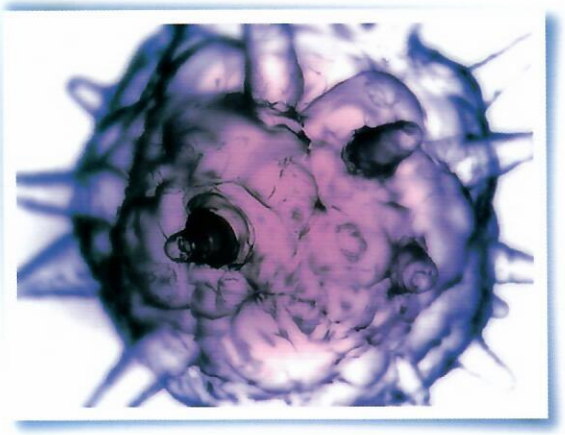
GLIZIGEN®

a highly effective product in the prophylaxis and treatment of human papillomavirus and genital herpes

The active principle of **GLIZIGEN®** is **glycyrrhizinic acid**, which is highly effective for the topical treatment of infections by herpesvirus (HSV) and human papillomavirus (HPV).

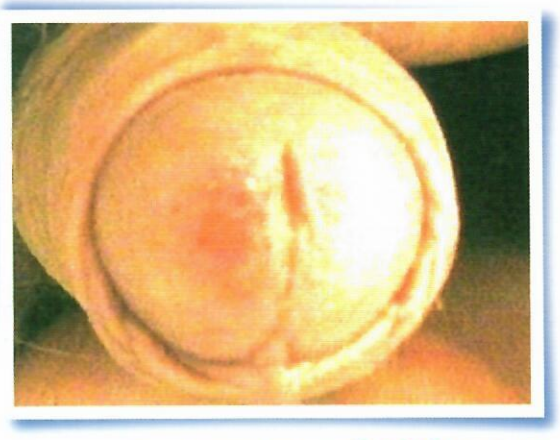
Glycyrrhizinic acid has been proposed as an antiviral against different viruses because it acts (in vitro and in vivo) preventing the replication of DNA and RNA viruses (VZV, HIV, influenza A and B, herpes simplex virus (HSV) 1 and 2, hepatitis B and C, amongst others).[1,2,3,4,5,6,7,8,9,10]

Clinical studies carried out on patients with different types of herpetic infections and papillomavirus demonstrate its efficacy.



herpes simplex virus

HSV



genital herpes treated with **GLIZIGEN®** for 5 days

In all treated patients the following was observed:

- High accelerated effectiveness in the initial and recurrent phases of infection by genital herpes, **with results in 12 days**.
- Excellent analgesic and anti-ulcerous effects from the first application.
- Excellent tolerance without irritation or side effects, even in pregnant women.
- Quick, easy, and hygienic application, which allows better adherence to the treatment.

GLIZIGEN® Intimate Gel is especially indicated for the daily intimate hygiene of both men and women.

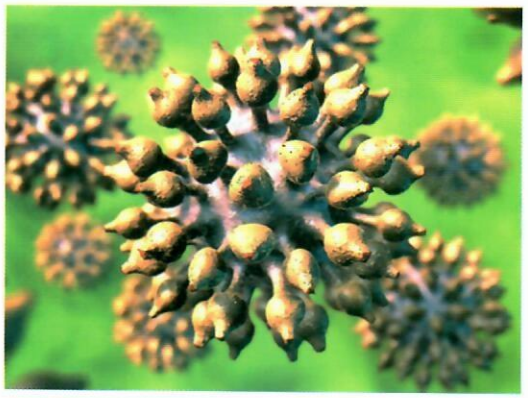
When it is used daily, it works like a prophylactic against HSV and HPV. It helps prevent any relapses too.

GLIZIGEN® is an alternative treatment for many patients who suffer from oral or genital (both herpetic vulvovaginitis and herpetic balanitis) herpes simplex, recurrent herpes simplex, herpes zoster, condyloma acuminatum and verruca vulgaris.

GLIZIGEN® is very well tolerated. No irritation or side effects of any kind have been reported.

Application is very easy and completely compatible with other types of systemic medication that the patient might be using.

The use of **GLIZIGEN®** is effective in the treatment of external genital warts, especially if they have not been treated previously.

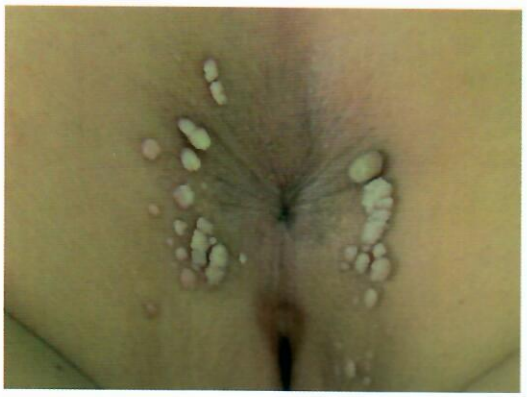


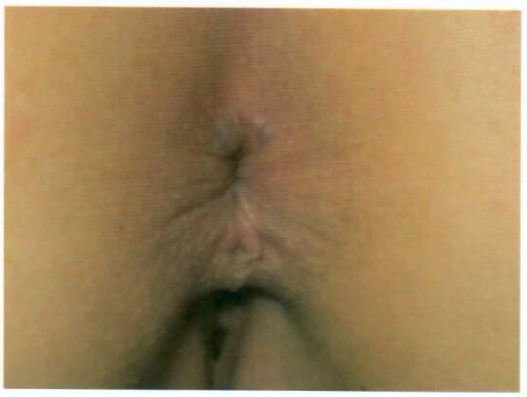
human papillomavirus

The best and quickest solution:

- Quick and easy to apply
- Extremely effective
- No side effects
- Completely innocuous
- Fast-acting

HPV





anogenital warts caused by human papillomavirus treated with **GLIZIGEN®** for 3 weeks

In all treated patients the following was observed:

- High effectiveness in viral negativization **in only 10 days, demonstrated by colposcopy and histopathology.**
- Excellent tolerance even with maximum doses used.
- No side effects.
- Greater therapeutic adherence.

GLIZIGEN® is completely compatible with other types of conventional therapy used. It does not cause any irritation and thanks to its natural ingredients, it does not have any side effects.

In some countries, **GLIZIGEN®** is marketed under the name of **EPIGEN®** or **HERPIGEN®**

ONCOXIN®

Oral Solution

an essential product in cancer therapy

ONCOXIN® Oral Solution is a specifically formulated nutrient that includes the most effective anti-cancer antioxidants, which have undergone a MOLECULAR ACTIVATION process that does not alter their structure. Furthermore, it boosts both their ANTIOXIDANT PROPERTIES and BIOLOGICAL ACTIVITY.

Green tea's polyphenols, and above all **epigallocatechin gallate**, present in **ONCOXIN®** Oral Solution, engage in highly relevant antimutagenic and anticarcinogenic activity in several types of tumours, as evidenced and described in many articles and journals published by leading US cancer research centres.

Epigallocatechin gallate is an active inhibitor of tumour growth and progression, which it achieves by either blocking the TNF-α's recipient, or deactivating the NFkB by preventing its nuclear translocation, and inhibition in the expression of COX-2, thus reducing incidence in the formation of pre-invasive injuries.(11,12,13,14)

Angiogenesis is a key process in tumour progression and metastasis. **Epigallocatechin gallate** halts this process by inhibiting the expression of proteins such as those found in the VEGF, as well as ephrin A1-induced cell migration.(15, 16, 17, 18, 19)

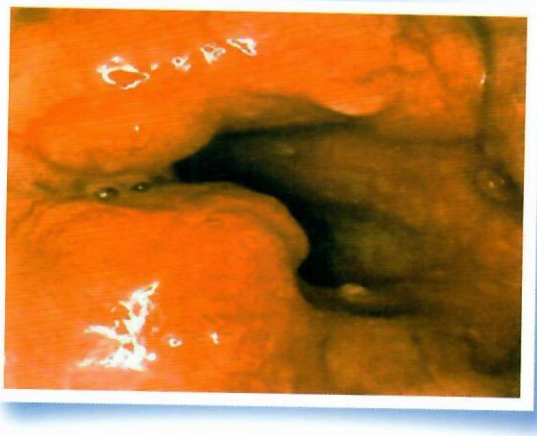
The expression and release of the cell matrix metalloproteinases (MMPs) 2 and 9 are connected with tumour cells' invasive process. **Epigallocatechin gallate** halts this process by inhibiting the expression of these two proteins.(20,21,22)

Epigallocatechin gallate restores apoptosis in tumour cells, as it selectively halts the cell cycle, and induces the expression of the proapoptotic proteins p53, caspasa-3, and Bax, as well as the inhibition of the antiapoptotic protein Bcl-2.(23,24,25,26,27,28)

Epigallocatechin gallate enhances cisplatin sensitivity and radiosensitivity in the tumour cells.(29, 30)

Using ONCOXIN® Oral Solution together with conventional cancer treatment increases the effectiveness of the latter and decreases the inherent side effects.(31)

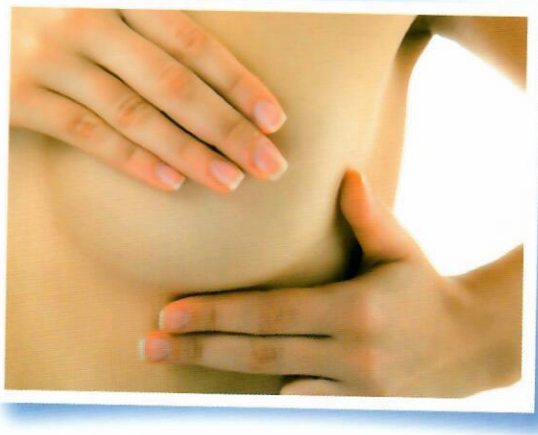
A powerful antioxidant with anticancer properties that helps patients tolerate conventional cancer treatment better

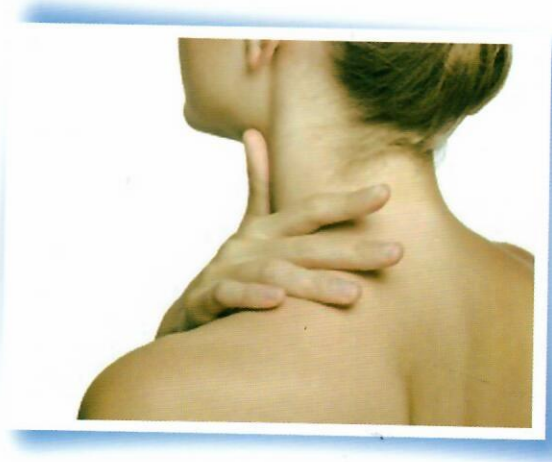


cervical uterine cancer

Clinical trials in which **ONCOXIN®** Oral Solution were was associated with chemotherapy and radiotherapy to treat head and neck cancer, breast and cervical uterine cancer, concluded that:

- **The patients' quality of life is much better.**
  Depression and psychic problems decrease.
- **Patients' trust in the effectiveness of the treatment increases.**
- **Patients show greater resistance to the oncologic treatment** as the frequency and intensity of side effects drop significantly.
- **Increased tolerance to chemotherapy and radiotherapy** has been observed gradually throughout the research, thus preventing the interruption of the treatment.
- **Decreased intensity of skin erythema**, dysphagia, mucus, and other types of erythema caused by radiotherapy.
- **Episodes of leukopenia are much less frequent** and even absent in the group treated with **ONCOXIN®** Oral Solution.
- **The Karnofsky Index remains stable after 12 months of treatment in 87% of the patients** treated with **ONCOXIN®** Oral Solution, compared with 47% of the patients who did not take it.
- **Weight clearly evolves** in favour of the patients who received **ONCOXIN®** Oral Solution as compared with the patients who were not.
- **Increased quality of life within 10 days, even for terminal patients.**





In some countries, **ONCOXIN®** Oral Solution is marketed under the name **ONCOXIN® + VIUSID®** Oral Solution

ONCOXIN®

Oral Solution

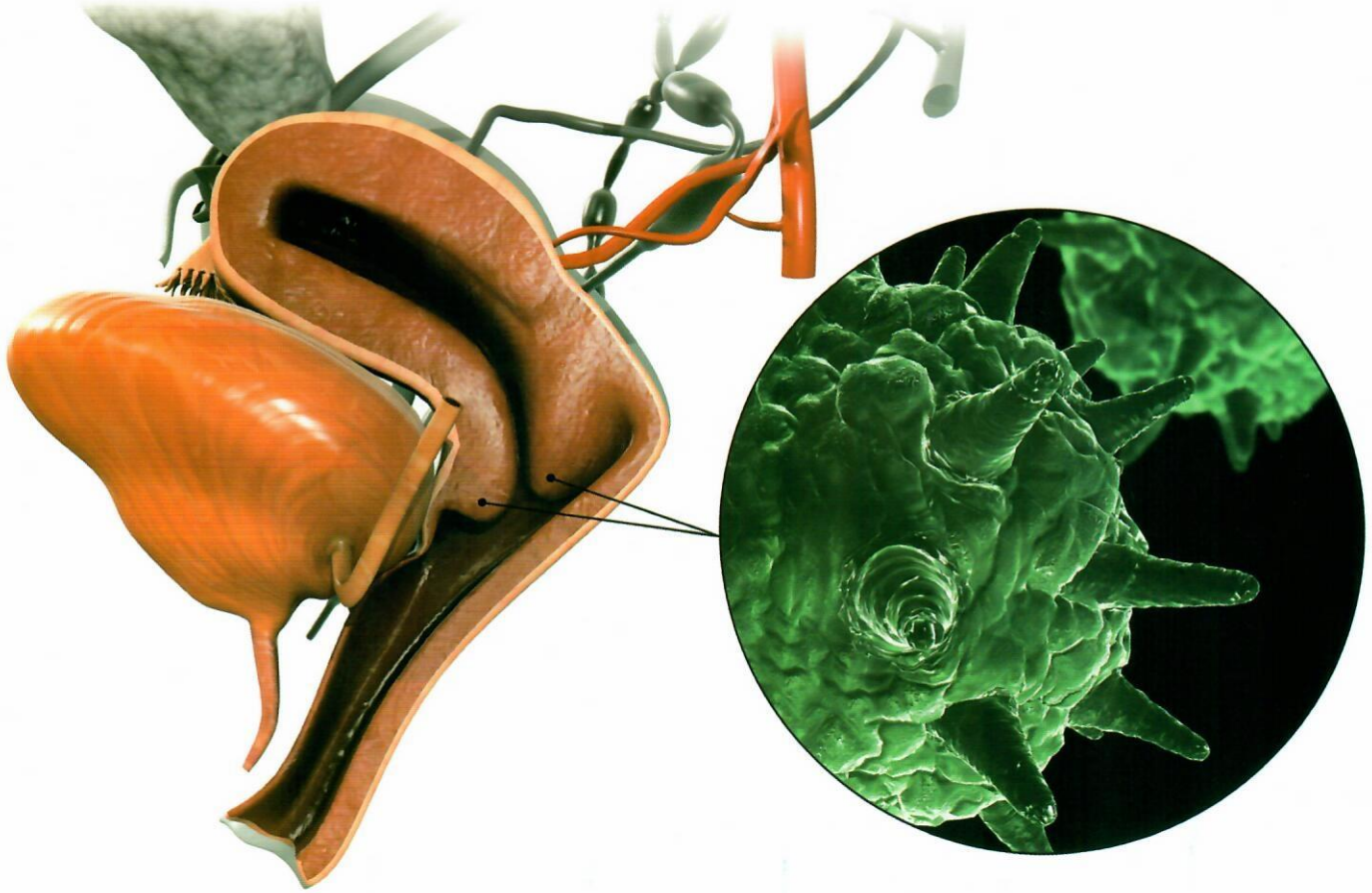
two complementary products used in the treatment of vulvar and cervical intraepithelial neoplasia (VIN and CIN)

In the year 2011, a **multicentre clinical trial was carried out with 11 patients to evaluate the effectiveness of using the products ONCOXIN® Oral Solution and GLIZIGEN® to treat high-grade cervical intraepithelial neoplasia and its relationship with the viral load of human papillomavirus.**

Hospital Docente Materno Infantil "10 de Octubre"
Instituto de Medicina Tropical "Pedro Kourí"
Hospital Docente "Ángel Arturo Aballí"

Coordinator: **Dr. Agueda Santana Martinez**

Havana • CUBA



GLIZIGEN®

SPECIFIC OBJECTIVES

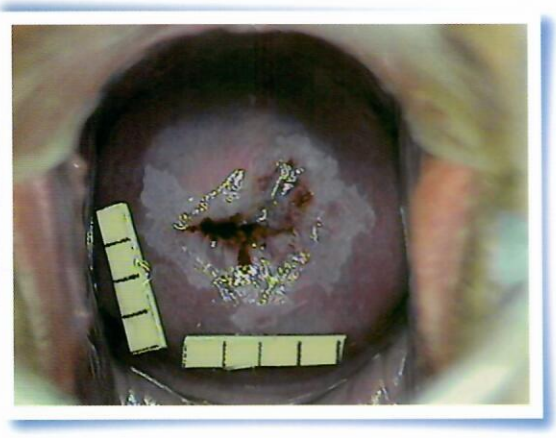
- To determine response to the treatment used according to colposcopy results and lesion histology.
- To determine the viral genotypes present in the cervical lesion together with viral load levels and persistence before and after the treatment has been administered.
- To describe the adverse effects during the treatment.

METHODOLOGY

- **ADMINISTRATION TIME**: 12 weeks.
- **TREATMENT USED**:
  - **GLIZIGEN®** Spray: Self-applied locally three times a day.
  - **GLIZIGEN®** Intimate Gel: Prophylactic once a day.
  - **ONCOXIN®** + **VIUSID®** Oral Solution: 25 ml three times a day.
- **CLINICAL TRIAL METHOD**:
  1. Evaluation before and after the treatment by means of a Pap smear and colposcopy.
  2. Samples of tissue obtained from a biopsy, histological and virological tests.
  3. Clinical-pathological response. Colposcopy to determine the favourable microscopic changes.
  4. Adverse events. Histological regression; pre-treatment punch biopsy, post-cone biopsy.
  5. Real time PCR of HPV: HPV types 16, 18, 31, 33, 45, and 58 are detected; the viral load of these types is quantified.
  6. Qualitative PCR of HPV: Only HPV+/HPV- are determined. HPV is identified by means of sequencing, viral load is not determined.
  7. Favourable virological response: Decrease in viral load, qualitative PCR not determined.

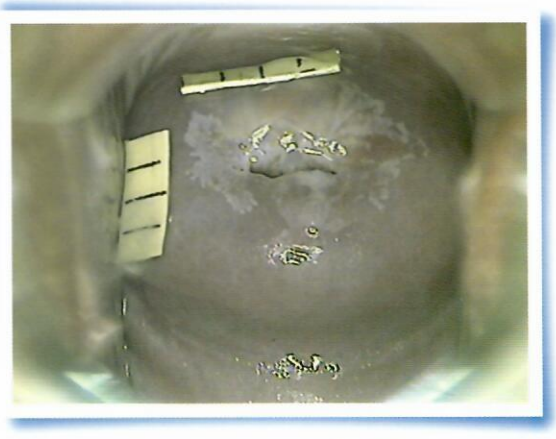
COMPLETE RESPONSE 10%

- **Case 1**



before treatment

Pap smear: Negative
Colposcopy: Dense acetowhite epithelium and irregular mosaic
Punch biopsy: CIN II
Viral load: 22 copies
Genotype: HPV 31

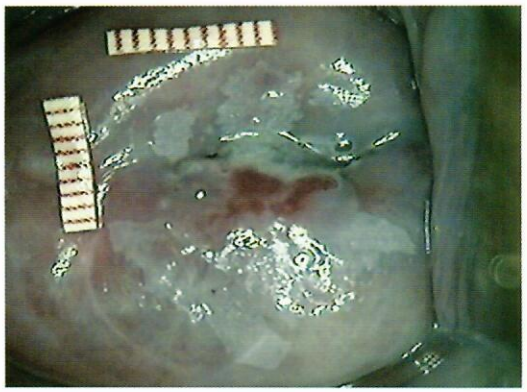


after 4 months of treatment

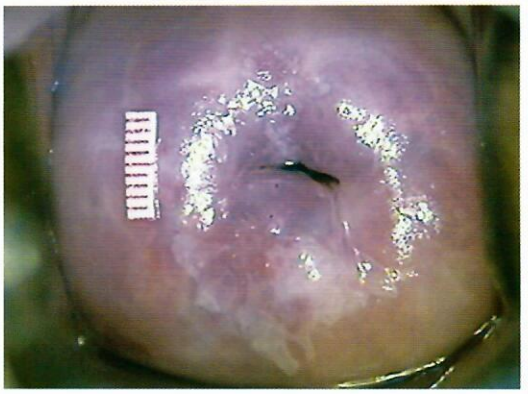
Colposcopy: Partial response
Post-cone biopsy: Chronic cervicitis
Viral load: Undetectable
Genotype: Undetermined
Cone evaluation: COMPLETE RESPONSE

PARTIAL RESPONSE 30%

- **Case 4**



before treatment



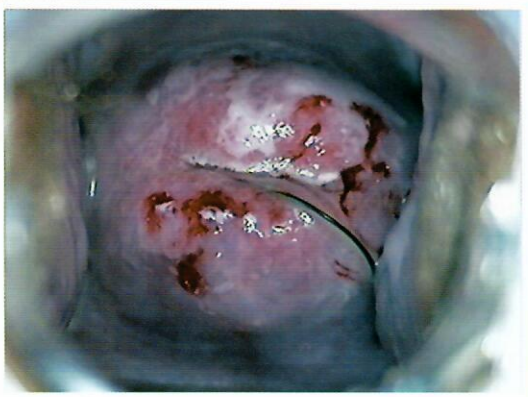
after 3 months of treatment

Pap smear: CIN I
Colposcopy: Acetowhite epithelium and mosaic
Punch biopsy: CIN II
Viral load: 6.9 x 10^3 copies
Genotype: HPV 16

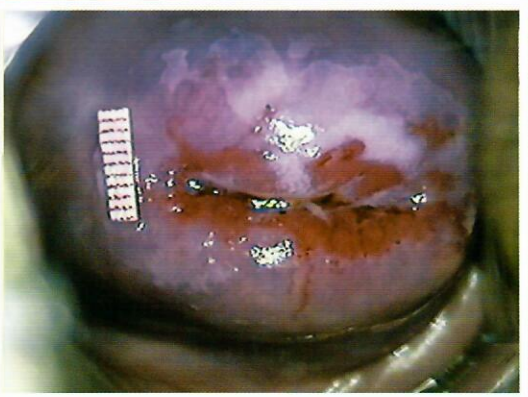
Colposcopy: Partial response
Post-cone biopsy: CIN I
Viral load: Undetectable
Genotype: Undetermined
Cone evaluation: PARTIAL RESPONSE

STABLE DISEASE 50%

- **Case 9**



before treatment



after 3 months of treatment

Pap smear: CIN II
Colposcopy: Dense acetowhite epithelium and red areas
Punch biopsy: CIS
Viral load: 6 x 10^6 copies
Genotypes: HPV 31

Colposcopy: Stable disease
Post-cone biopsy: CIN III/CIN I
Viral load: 1 x 10^6 copies
Genotype: HPV 31
Cone evaluation: STABLE DISEASE

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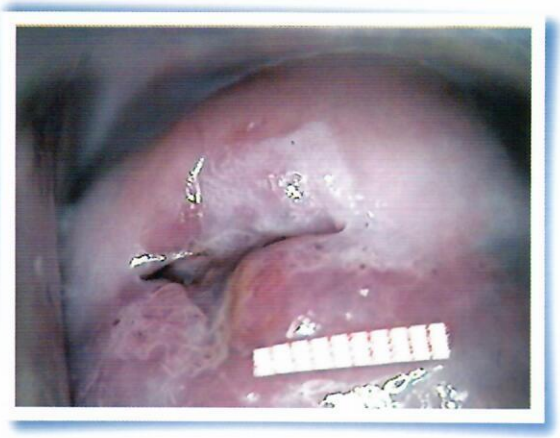
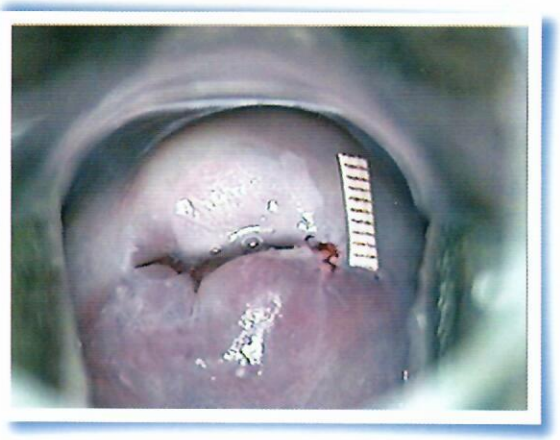
PROGRESSIVE DISEASE 10%

- **Case 5**



before treatment

Pap smear: CIN I
Colposcopy: Dense acetowhite epithelium
Punch biopsy: CIN II
Viral load: 3.9 x 10^3 copies
Genotypes: HPV 16



after 3 months of treatment

Colposcopy: Partial response
Post-cone biopsy: CIN III
Viral load: 4 x 10^5 copies
Genotype: HPV 16
Cone evaluation: PROGRESSIVE DISEASE

CONCLUSIONS

- The results of the colposcopic and histological evaluations highlight a slightly favourable response to the combined use of **GLIZIGEN®** + **ONCOXIN®** Oral Solution.
- The anti-inflammatory response in the lesions treated with the product was demonstrated.
- There were very few and very slight adverse events observed during the treatment.
- 100% of the initial samples are positive to oncogenic HPV.
- The predominant viral genotypes are 16 and 31. No association with the response to the therapy is made.
- The decrease in the viral load levels and in the viral persistence shows that the treatment with **GLIZIGEN®** + **ONCOXIN®** Oral Solution could indeed be effective in controlling HPV infection.
- When the combination of **GLIZIGEN®** + **ONCOXIN®** Oral Solution is used, in the short-term, the virological response is seen to be better than the clinical-pathological response.

GLIZIGEN® + ONCOXIN® Oral Solution is an adjuvant treatment for high-grade vulvar and cervical intraepithelial neoplasia in adolescent and young women; it does not have side effects and it reduces the risk of a relapse

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PROPHYLAXIS AND TREATMENT OF VULVAR AND CERVICAL INTRAEPITHELIAL NEOPLASIA (VIN AND CIN)

GLIZIGEN®

Composition GLIZIGEN® spray, labial, and intimate gel:

Glycyrrhizinic Acid	0,1 g
Excipients, s.q.f.	100 ml

Posology / Administration

GLIZIGEN® spray:

Genital herpes: 3 - 4 nebulizations per day for 5 days.
Varicella-zoster herpes: 3 - 4 nebulizations per day for 7 - 10 days.
Papillomavirus with small initial condylomas: directly by irrigation of the affected area with **GLIZIGEN®** 4 - 5 nebulizations per day for 7 days.
In patients with large, long-term condyloma, **GLIZIGEN®** is best used in combination with cryodispersion or cryodestruction, etc. Apply the nebulizations on the affected areas. (One nebulization corresponds to two short pressings on the nebulizer.) As administration is topical and there is virtually no absorption through the skin and mucosae, it is not necessary to determine a maximum admissible dose. Once applied, the product acts for approximately 6 - 8 hours.

GLIZIGEN® labial:

Oral herpes : Apply regularly a sufficient quantity to cover the surface of the lips. If necessary, apply 3 - 5 times per day for 5 days to quickly improve the state of the lips. In very severe cases, the treatment may be prolonged for more days without any problem.

GLIZIGEN® intimate gel:

Especially indicated for the daily intimate hygiene of both men and women, in gynaecological treatment as a prophylactic to be used daily and for cleansing prior to applying any gynaecological treatment. Apply to the previously moistened skin or mucous membranes. Rinse with plenty of water. It can also be diluted in the water of the bidet or used with the daily shower. Rinse thoroughly.

Presentation

60 ml **spray** with applicator
5 ml lip **cream**
250 ml **intimate gel**

ONCOXIN®

Oral Solution

Average Values (per 100 ml)

Glycine	2,000 mg	Green Tea Extract	25 mg
Glucosamine	2,000 mg	Calcium Pantothenate	12 mg
Malic Acid	1,200 mg	Pyridoxine	4 mg
Arginine	640 mg	Manganese Sulphate	4 mg
Cysteine	204 mg	Cinnamon Extract	3 mg
Mono-Ammonium Glycyrrhizinate	200 mg	Folic Acid	400 µg
Ascorbic Acid	120 mg	Cyanocobalamin	2 µg
Zinc Sulphate	80 mg		

Dosage / Administration

ONCOXIN® Oral Solution must be taken after main meals.

- Adults:
  25 ml of **ONCOXIN® Oral Solution** every twelve hours.
- Children aged 6 and over:
  12.5 ml of **ONCOXIN® Oral Solution** every twelve hours.

Length of Treatment

The treatment must be applied for at least 6 months.
ONCOXIN® Oral Solution may be taken for longer periods of time with no risk whatsoever of side effects.

Presentation

500 ml bottle of **Oral Solution** with dispenser

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