Allomedin®

Summary of clinical studies

1. Description

Allomedin® is a hydrogel designed to protect skin against cold sores and other lesions caused by HSV and HPV infections. It is currently registered as cosmetic products. However, long term studies and clinical tests demonstrated that it not only improves the appearance of the skin but also has a pronounced therapeutic effect due to the presence of the active ingredient Allostatine in its composition. Allostatine is a synthetic peptide designed to activate residential immune cells (NK and T lymphocytes) functionality and enhance by this way skin and mucosa natural resistance to HSV and HPV infections. Moreover, Allomedin® contains additional compounds commonly used in dermatological and cosmetic products: carbopol, allantoin, phenoxyethanol, ethylhexylglycerin, sodium hydroxide.

This review summarizes the results of a clinical study of Allomedin therapeutic activity and safety in addition to previously published materials.

2. Allomedin clinical efficacy

Allomedin therapeutic efficacy and safety had been clinically evaluated in specialized clinics, hospitals and medical centers as follows:

1. Russian medical academy of postgraduate education, St. Petersburg (dermatology and cosmetology department, stomatology department)
2. St. Petersburg city center for prevention of infectious diseases
3. Pasteur research institute, St. Petersburg
4. Center for preventive Medicine, St. Petersburg
5. Center of clinical immunology, St. Petersburg
6. Republican clinical hospital for infectious diseases
7. First St. Petersburg medical university (department of otorhinolaryngology)
8. District antenatal clinic №1, St. Petersburg
9. District antenatal clinic №2, St. Petersburg
10. Medical university, Petrozavodsk

A total of 168 patients with herpes and 272 patients with HPV are included in this clinical study.

2.1. Herpes simplex virus (HSV) infections

Clinical data characterizing Allomedin therapeutic efficacy in patients infected with *Herpes simplex* virus include 104 patients (81 females, 23 males) experiencing relapsing herpes of different localization more than 4 years before the study. Age of the patients was varied from 18 to 60 years. Allomedin was applied onto the surface of herpetic lesions 2 to 3 times a day during 3 to 5 days. Results of the studies are summarized in the Table 1.

Table 1. Allomedin clinical efficacy in the therapy of herpes relapses with reference to the lesion's localization (summary of multicenter clinical study).

Localization	**Therapeutic efficacy evaluation**		
	Patients number	**Positive responses**	
		N	**%**
Skin	27	26	96,3
Vagina or urethra mucous tunic	44	41	93,1
Mouth mucous tunic	33	20	66,6

Data of Table 1 demonstrate that absolute majority of patients with skin herpes and genitalia mucous tunic herpes (labial and genital herpes, correspondingly) can be effectively treated by Allomedin.

Clinical studies of Allomedin efficacy in labial and genital herpes demonstrated also extraordinary fast relief of herpes symptoms elimination compared to the standard antiviral therapy. Tables 2 and 3 illustrate this fact. Allomedin rapidly eliminates inflammation symptoms like itch, burning, oedema so that duration of the symptoms decreases about **10 times** compared to acyclovir treatment.

Table 2. Allomedin and acyclovir comparative efficacy in the treatment of cold sores (labial herpes) symptoms (data of the Center of clinical immunology, St. Petersburg).

Index	The index rate, hours	
	Acyclovir	Allomedin
Itchiness and burning duration	60 - 84	4-8
50% decrease in the size of the oedema zone	84 -108	8-12
Total relapse duration	168 - 192	72 - 96

Table 3. Allomedin and acyclovir comparative efficacy in the elimination of genital herpes symptoms (data of the Pasteur research institute, St. Petersburg).

Indices and stages	Symptoms duration, hours	
	Acyclovir	Allomedin
Itch	84,3 ± 9,4	13,6 ± 3,7
Burning	93,2 ± 12,8	14,0 ± 2,2
Vesicular-erosive stage	96,2 ± 12,8	54,6 ± 10,2
Scab stage	114,1 ± 20,8	98,0 ± 12,8

2.2. Human papilloma virus (HPV) infections.

Clinical data characterizing Allomedin therapeutic efficacy in patients infected with human papilloma virus include 296 patients (80 males, 216 females). Age of the patients was varied from 18 to 60 years. Allomedin was applied onto the surface of HPV infected area 2 to 3 times a day during 7 to 10 days. Results of the studies are summarized in the Table 4. Clinical trials demonstrated high Allomedin efficacy in the treatment of HPV infection of different localization. Number of patients positively responding to the treatment was varying in the range 80-90 % depending on the localization and according to the therapeutic efficacy criteria used in the clinic.

Table 4. Allomedin clinical efficacy in the therapy of HPV infection with reference to the lesion's localization (summary of multicenter clinical study).

Localization	Therapeutic efficacy evaluation		
	Patients number	Positive responses	
		N	%
Skin	57	50	87,7
Vagina or urethra mucous tunic	176	152	86,3
Mouth, nose and throat mucous tunic	63	52	82,5

Long term clinical study conducted in the onco-gynecology division of the Center for preventive medicine allows comparing therapeutic efficacy of Allomedin and standard therapies in patients suffering with cervicovaginal intraepithelial dysplasia caused by highly oncogenic HPV types 16 or 18. Response was recognized as positive when PCR diagnostic confirmed absence of the virus in the treated area during one month post treatment and physical examination registered disappearance of the dysplasia manifestation. Results of the study are summarized in the Table 5. Combination of two antiviral drugs (acyclovir and neovir) demonstrated relatively low efficacy in case of cervicovaginal HPV infection. Cryodestruction had partial efficacy regarding elimination of HPV infection while Allomedin demonstrated clear advantage compared to both methods. Important to note that Cryodestruction

(treatment of infected area with liquid nitrogen) is recognized worldwide as golden standard of cervical HPV infection therapy in spite of significant damaging of the reproductive organ. No harmful effects of Allomedin application were found in this and other clinical studies.

Table 5. Comparative therapeutic efficacy of Allomedin, combined antiviral therapy (acyclovir + neovir) and cryodestructive therapy in patients with cervicovaginal intraepithelial dysplasia caused by oncogenic HPV types 16/18.

Treatment	Patients number	Positive responses (%)
Combined antiviral therapy (acyclovir + neovir)	19	26,6
Cryodestructive therapy	60	53,3
Allomedin	150	77.6

Allomedin efficacy against HPV infection was also compared with injectable formulation of Alloferon, Allostatin naturally occurring precursor registered in Russia as antiviral drug. Clinical study conducted in Petrozavodsk Medical university included 45 women (age 17-45 years) with cervicovaginal infection caused by highly oncogenic HPV types 16 or 18 (43 patients) or moderately oncogenic HPV types 31 or 32 (2 patients). 20 patients received Allomedin applications 2 times a day during 5 to 7 days (group I). 21 patients (group II) received Alloferon (registered trade name “Allokine-Alpha”) subcutaneous injections (3 injections by 1 mg). 4 patients (group III) were treated with combination of Allomedin applications and Alloferon injections. The patients were examined during 3 to 12 months post treatment using set of clinical analyses (physical examination, advanced colposcopy, Papanicolaou assay, biopath analysis, viral DNA PCR analysis). Results are summarized in Table 6.

Table 6. Comparative study of Allomedin topical applications and Alloferon injections therapeutic efficacy in patients with cervicovaginal HPV infections.

Treatment	Patients number	Positive responses			
		Clinical manifestation		Viral DNA elimination (PCR analysis)	
		N	%	N	%
Allomedin	20	17	85	19	95
Alloferon	21	9	43	12	57

3. Conclusion

Long term preclinical and clinical studies demonstrated extraordinary therapeutic efficacy of Allomedin in the therapy of skin and mucous tunic HSV and HPV infections. To our best knowledge there is no drug or cosmeceutical that could be as effective as Allomedin in this field for the time being.