

Application of the method of enterosorption therapy by silicon enterosorbent Enterosgel in the integrated treatment of allergic diseases

Clinical research assessment – A concluding statement 2009

Goal of the research

Verification of clinical effectiveness and monitoring of the laboratory values profile in patients with dermatologic (atopic dermatitis, hives) and respiratory (allergic asthma and allergic rhinitis) allergic symptoms in the period of main disease recrudescence. The influence of ENTEROSGEL taken was tested as a complementary influence in terms of the conventional basic treatment. For the purpose of making comparisons the same group of patients was monitored within the period prior to application of ENTEROSGEL.

A group of patients and methods used

This monitoring involved 24 patients (10 men and 14 women aged from 2 to 80 years, average age is 43,1) with the diagnosis: stable mild or moderate bronchial asthma (6 patients), chronic hives (7 patients), stable atopic eczema (6 patients) and 5 patients with other diagnosis (a case of polyvalent allergy with apparent digestive disorders, a case of food allergy, 2 cases of chronic fatigue syndrome and a case of chronic uveitis and keratitis with recurrent stomatitis), which arrived at the allergological outpatient department concerning deterioration of their disorders or in relation to the regular control over their medical condition.

The point-based assessment was carried out 3 weeks prior to the commencement of treatment with ENTEROSGEL (the control group), and further within 3 weeks of a regular taking of ENTEROSGEL (the group of intensive influence).

The group members after familiarization with the research according to the inclusion or exclusion criteria:
Basic inclusion criteria:

1. Patients over 2 years with an allergic disease (see above – a group of patients)
2. Patients with the prerequisite to cooperate properly in the course of research, which gave a written informed consent to participate in the research.

Basic exclusion criteria:

1. Hypersensitivity to the medical product ENTEROSGEL in the medical background
2. Patients with no prerequisite to cooperate properly in the course of research
3. Absence of a written consent to participate in the research
4. Participation in any other research within the previous 3 months
5. Patients treated with enterosorbents, probiotics and prebiotics within the last 30 days.

Patients which after their signing the written informed consent were given the PATIENT'S DIARY to record their point-based assessments of their disorders regarding individual researched diseases

Dosage:

- Medication intake 3 times a day of 1 tablespoon (15 g), stirred in a glass of water, i.e. a daily dose makes 45g taken 2 hours after meals or 1 – 2 hours before meals.

- An adequate consumption of water was recommended to hydrate the patient in course of treatment by Enterosgel, i.e. not less than 2 liters of liquids per day.

- Children under 6 – 1 teaspoon of Enterosgel (up to 5 g), i.e. a daily dose makes 15g in the same regimen – see above provided the consumption of no less than 0,5 liters of liquids per day is ensured.

In the course of the research the following medication products were forbidden to be used: any enterosorbents, prebiotics and probiotics.

The following drugs were allowed to be used in the course of the research: all drugs previously taken by the patients as well as such drugs which are officially accepted by modern standards for treatment of the specified diseases.

Point-based symptom assessment.

Within 21 days prior to applying Enterosgel the results of the point-based assessment made by the patients were evaluated (individual monitored symptoms - see the table in the Patient’s diary regarding individual diseases). The initial value was equal to 3 points which corresponded to the symptoms as of the monitoring commencement date. Within the following days the patient assessed his symptoms in the range from 1 point to 5 points (see the Diaries). This period was used as a comparative-control group. The patients also assessed their own symptoms in points within individual days of being treated with Enterosgel and did it in the identical way.

The Diary of the patient with bronchial asthma

| Day | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|
| General well-being | 3 | | | | | | | | | | | | | | | | | | | | | |
| Dyspnea | 3 | | | | | | | | | | | | | | | | | | | | | |
| Sibilant rale | 3 | | | | | | | | | | | | | | | | | | | | | |
| A feeling of chest congestion | 3 | | | | | | | | | | | | | | | | | | | | | |
| Cough | 3 | | | | | | | | | | | | | | | | | | | | | |
| Night dyspnea | 3 | | | | | | | | | | | | | | | | | | | | | |
| The quality of sleep | 3 | | | | | | | | | | | | | | | | | | | | | |
| Everyday activities | 3 | | | | | | | | | | | | | | | | | | | | | |

1 – significant deterioration 2 - deterioration 3 – current condition 4 - improvement 5 – significant improvement

The Diary of the patient with atopic eczema

| Day | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|--------------------------|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|
| General well-being | 3 | | | | | | | | | | | | | | | | | | | | | |
| Reddening | 3 | | | | | | | | | | | | | | | | | | | | | |
| New loci | 3 | | | | | | | | | | | | | | | | | | | | | |
| Weeping eczema condition | 3 | | | | | | | | | | | | | | | | | | | | | |
| Rash | 3 | | | | | | | | | | | | | | | | | | | | | |
| Dry skin | 3 | | | | | | | | | | | | | | | | | | | | | |
| Itching | 3 | | | | | | | | | | | | | | | | | | | | | |
| The quality of sleep | 3 | | | | | | | | | | | | | | | | | | | | | |
| Everyday activities | 3 | | | | | | | | | | | | | | | | | | | | | |

1 – significant deterioration 2 - deterioration 3 – current condition 4 - improvement 5 – significant improvement

The Diary of the patient with chronic hives

| Day | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|----------------------|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|
| General well-being | 3 | | | | | | | | | | | | | | | | | | | | | |
| New loci | 3 | | | | | | | | | | | | | | | | | | | | | |
| The size of the sore | 3 | | | | | | | | | | | | | | | | | | | | | |
| Itching | 3 | | | | | | | | | | | | | | | | | | | | | |
| Rash | 3 | | | | | | | | | | | | | | | | | | | | | |
| Oedema, face | 3 | | | | | | | | | | | | | | | | | | | | | |
| The quality of sleep | 3 | | | | | | | | | | | | | | | | | | | | | |
| Everyday activities | 3 | | | | | | | | | | | | | | | | | | | | | |

1 – significant deterioration 2 - deterioration 3 – current condition 4 - improvement 5 – significant improvement

The point-based assessment of the patients with other diseases concerned the following: perception of the general well-being, the quality of sleep, everyday activities, headache, abdominal pain, joint and muscle pain, stool regularity.

Laboratory researches:

They were performed for all the patients at the first examination (Day 0) and at the second examination (Day 21 – prior to the commencement of Enterogel application) and at the third examination (Day 42 - that is integrally 21 days after the initial application of Enterogel): total levels of IgE, specific IgE as a response to the causative allergens (according to the medical background or to the previous dermatic tests), urea, creatinine, bilirubin, cholesterol, alanine-aminotransferase, AST, AMS

| | Selection 1 (Day 0) | Selection 2 (Day 21) | Selection 3 (Day 42) |
|--------------|---------------------|----------------------|----------------------|
| Total IgE | | | |
| Specific IgE | | | |
| Urea | | | |
| Creatinin | | | |
| Bilirubin | | | |
| Cholesterol | | | |
| ALT | | | |
| AST | | | |
| AMS | | | |

Spirometry

It was performed for the patients with the diagnosis: bronchial asthma at examinations No. 1, 2 and 3 (days 0, 21st, 42nd)

Statistical estimation.

It was performed in the department of statistics of the Institute of biophysics (Mgr.Langrová) according to the rectilinear regression method pursuant to which linear regressions were determined for each and every patient for the period without treatment and with treatment subsequent to which average regression coefficient values and absolute intercepts were determined under paired Sign test.

Where the normality tests confirmed normal distribution of absolute intercepts and coefficient, paired Sign tests were performed for all the values. Provided the data obtained from the normality test did not show the normality of distribution, the consecutive paired test of Wilcoxon was performed.

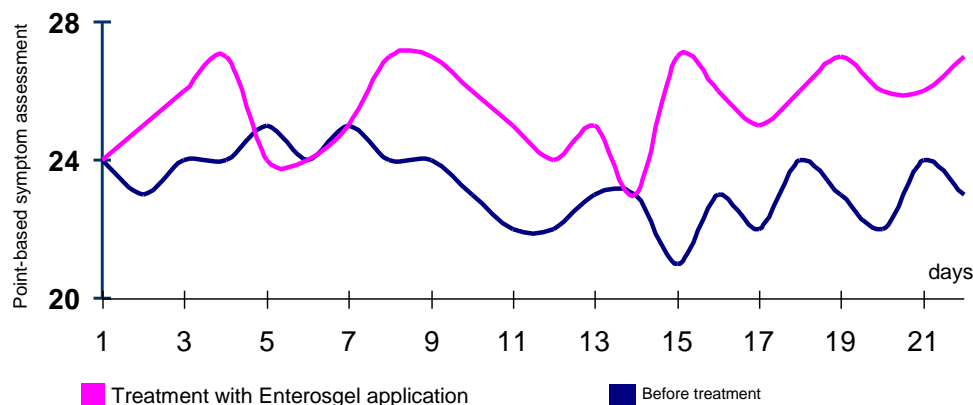
Results

1. Monitoring of the point-based assessment of symptoms in the patients with bronchial asthma.

The following table shows the values of the point-based assessment of symptoms by individual patients within the period before the commencement of Enterogel application as well as within the subsequent 21 day-period of its application. With respect to the initial point-based value, the current status makes 24 points – see the Patient's diary. The graph below is constructed subject to average values of the point-based assessment of symptoms for individual days of monitoring.

The control and intensively treated group of patients with bronchial asthma

Enterogel – influence over the point-based symptom assessment in the patients with bronchial asthma



Statistical significance of the changes $P = 0,024$ evidences statistically significant improvement of the point-based assessment in the group under Enterogel's intensive influence.

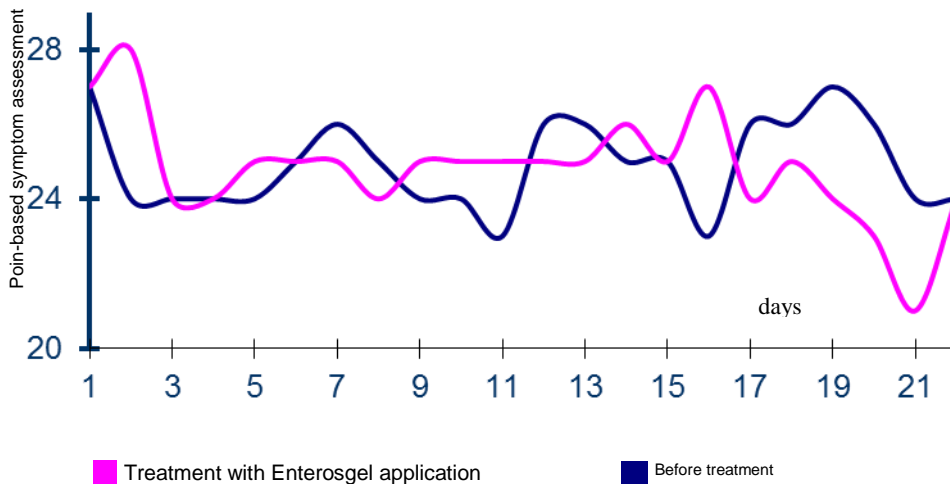
2. Monitoring of the point-based assessment of symptoms in the patients with atopic eczema.

Below the values of the point-based assessment of symptoms by patients within the period before the commencement of Enterosgel application as well as within the subsequent 21 day-period of its application are given. With respect to the initial point-based value, the current status makes 27 points – see the Patient’s diary. The graph below is constructed subject to average values of the point-based assessment of symptoms for individual days of monitoring.

The control and intensively treated group of patients with atopic eczema

| | | | | | | | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | |
| 27 | 27 | 27 | 24 | 24 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 |
| 27 | 24 | 27 | 23 | 25 | 23 | 26 | 27 | 27 | 28 | 25 | 25 | 26 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 |
| 27 | 17 | 17 | 22 | 20 | 21 | 24 | 22 | 22 | 23 | 26 | 26 | 25 | 25 | 26 | 16 | 20 | 22 | 27 | 18 | 18 | 18 | 18 |
| 27 | 21 | 20 | 21 | 21 | 22 | 23 | 24 | 20 | 22 | 21 | 23 | 22 | 21 | 24 | 24 | 26 | 27 | 27 | 27 | 27 | 27 | 27 |
| 27 | 27 | 23 | 28 | 28 | 30 | 30 | 22 | 19 | 15 | 15 | 29 | 26 | 25 | 20 | 19 | 27 | 27 | 27 | 27 | 27 | 19 | 20 |
| 27 | 27 | 27 | 24 | 25 | 27 | 27 | 27 | 26 | 26 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 | 27 |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | |
| 27 | 38 | 38 | 38 | 37 | 33 | 33 | 33 | 32 | 30 | 35 | 34 | 33 | 32 | 32 | 30 | 28 | 27 | 25 | 22 | 21 | 21 | 21 |
| 27 | 24 | 22 | 23 | 23 | 25 | 28 | 31 | 29 | 28 | 28 | 28 | 26 | 27 | 28 | 31 | 26 | 24 | 27 | 22 | 22 | 32 | 32 |
| 27 | 26 | 12 | 12 | 14 | 16 | 19 | 14 | 17 | 18 | 16 | 16 | 16 | 19 | 21 | 22 | 25 | 23 | 24 | 23 | 23 | 23 | 24 |
| 27 | 27 | 27 | 27 | 21 | 21 | 21 | 21 | 21 | 27 | 27 | 27 | 26 | 26 | 25 | 21 | 21 | 21 | 18 | 18 | 18 | 21 | 21 |
| 27 | 27 | 21 | 21 | 28 | 30 | 22 | 22 | 26 | 21 | 19 | 20 | 24 | 26 | 18 | 32 | 18 | 32 | 27 | 28 | 21 | 21 | 21 |
| 27 | 27 | 26 | | | | | | | | | | | | | | | | | | | | |

Enterosgel – influence over the point-based symptom assessment in the patients with atopic eczema



Statistical significance of the changes $P = 0,049$ does not evidence statistically significant influence of Enterosgel application on the change of the point-based symptom assessment by the patients with atopic eczema.

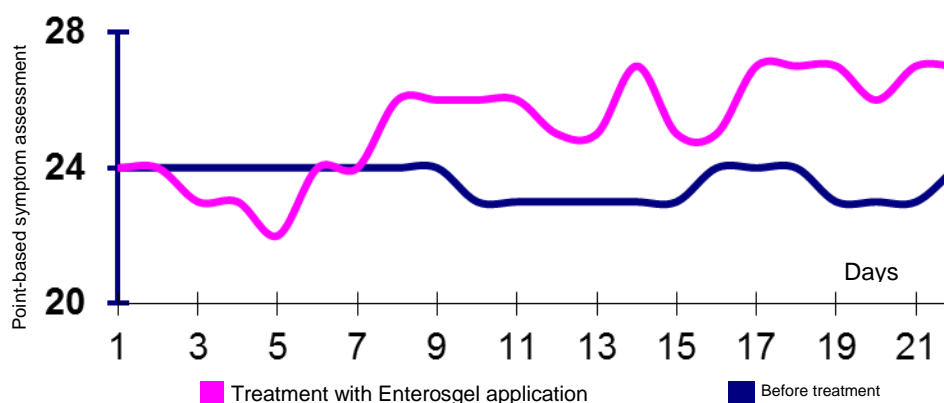
3. Monitoring of the point-based assessment of symptoms in the patients with chronic hives.

The following table shows the values of the point-based assessment of symptoms by individual patients within the period before the commencement of Enterosgel application as well as within the subsequent 21 day-period of its application. With respect to the initial point-based value, the current status makes 24 points – see the Patient’s diary. The graph below is constructed subject to average values of the point-based assessment of symptoms for individual days of monitoring.

The control and intensively treated group of patients with chronic hives

| | | | | | | | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 25 | 25 | 22 | 22 | 22 | 20 | 20 | 20 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 22 | 22 | 22 | 22 | 22 | 22 | 24 | 24 | 24 | 24 | 20 | 20 | 20 | 24 | 24 | 24 |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 24 | 24 | 22 | 25 | 24 | 24 | 24 | 22 | 23 | 23 | 24 | 23 | 23 | 23 | 23 | 23 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | |
| 24 | 24 | 24 | 24 | 24 | 24 | 24 | 24 | 26 | 26 | 26 | 24 | 26 | 26 | 27 | 27 | 26 | 28 | 28 | 28 | 28 | 28 | 28 |
| 24 | 22 | 22 | 20 | 20 | 20 | 22 | 22 | 20 | 20 | 20 | 22 | 22 | 23 | 22 | 23 | 22 | 23 | 22 | 23 | 23 | 22 | 21 |
| 24 | 24 | 22 | 24 | 22 | 18 | 19 | 24 | 24 | 24 | 24 | 18 | 20 | 25 | 25 | 24 | 24 | 21 | 19 | 25 | 25 | 23 | 23 |
| 24 | 23 | 23 | 23 | 22 | 23 | 23 | 24 | 23 | 22 | 22 | 24 | 24 | 26 | 27 | 26 | 29 | 30 | 28 | 28 | 28 | 28 | 29 |
| 24 | 26 | 18 | 21 | 23 | 23 | 27 | 30 | 30 | 30 | 30 | 28 | 29 | 30 | 30 | 31 | 31 | 31 | 31 | 31 | 31 | 31 | 31 |
| 24 | 23 | 23 | 23 | 20 | 20 | 20 | 23 | 23 | 23 | 23 | 23 | 23 | 23 | 23 | 22 | 22 | 23 | 23 | 23 | 23 | 23 | 24 |
| 24 | 25 | 30 | 24 | 25 | 37 | 36 | 37 | 37 | 37 | 37 | 37 | 37 | 38 | 22 | 27 | 30 | 36 | 36 | 25 | 31 | 32 | 32 |

Enterosgel – influence over the point-based symptom assessment in the patients with chronic hives



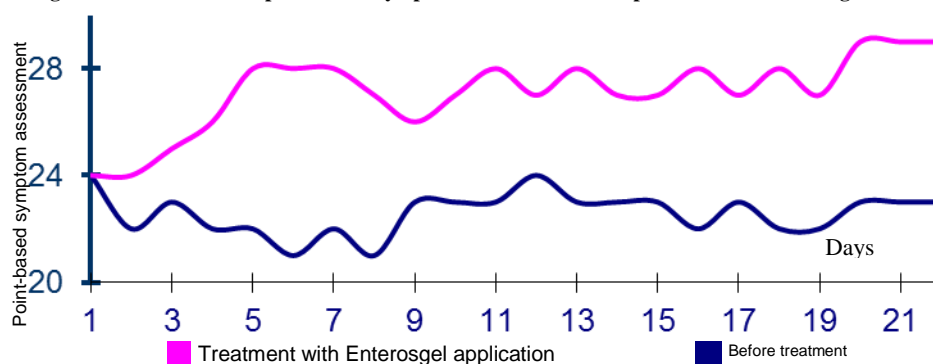
Statistical significance of the changes $P = 0,027$ evidences statistically significant improvement of the point-based assessment in the group under Enterosgel's intensive influence.

4. Monitoring of the patients with other diagnoses.

The following table shows the values of the point-based assessment of symptoms by individual patients within the period before the commencement of Enterosgel application as well as within the sunsequent 21 day-period of its application. With respect to the initial point-based value, the current status makes 24 points – see the Patient's diary. The graph below is constructed subject to average values.

The control and intensively treated group of patients with other diagnoses

Enterosgel – influence over the point-based symptom assessment in the patients with other diagnosis

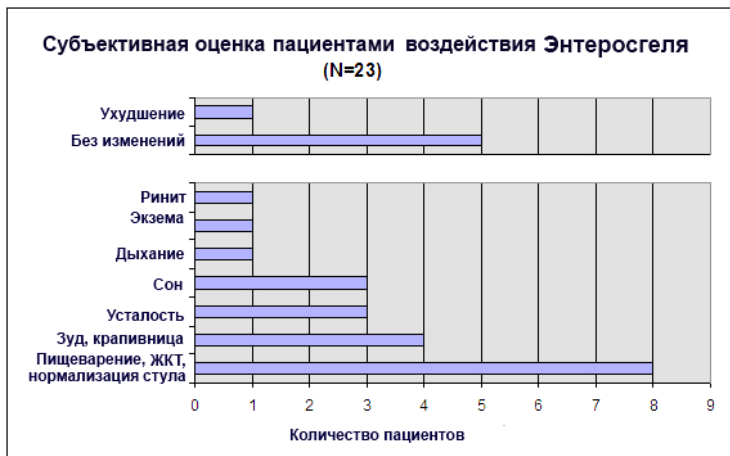


Statistical significance of the changes $P = 0,004$ evidences statistically significant improvement of the point-based assessment in the group under Enterosgel's intensive influence.

5. Subjective evaluation of the therapeutic effect on part of the patients.

After the application of Enterosgel came to an end the patients were provided with the questionnaire regarding general impression of taking the medical product; it contained questions whether the application had deteriorated the main disease, whether the condition was left unchanged, whether there was any improvement in basic manifestations of the main disease, whether there was a significant improvement in health condition. Further the patients were able to point the subjective feeling which they had realized most evidently in the course of treatment.

The following diagram shows that only one patient assesses the application as unsuccessful having no tolerance to it. Intolerance also persisted after the dosage and taste of the drug had been changed, that is why the treatment was broken off. 5 patients showed that they had not experienced any changes in their health condition. 17 patients (i.e. 74%) assessed the application as favorable. The following table shows favorable influence factors experienced by the patients taking Enterosgel.



The table translation: Subjective evaluation of Enterosgel influence made by the patients.

- Deterioration
- No changes
- Rhinitis
- Eczema
- Breath
- Sleep
- Fatigue
- Itching, hives
- Digestion, gastrointestinal tract
- Normalization of stool
- Number of patients

Noticed improvement in health condition apart from the main disease

- Digestion improvement, removal of digestive disorders, normalization of stool - 35%
- Improvement in the itching condition, hives - 17%
- Improvement in fatigue state - 13%
- Sleep improvement - 13%
- Breath improvement - 4%
- Reduction in allergic rhinitis manifestations - 4%
- Reduction in food allergy manifestations - 4%
- Eczema improvement - 4%

Deterioration or unfavorable influence

- vomiting, necessity to break prematurely off (after 3 days of application)
- no improvement after reduction of dosage and change of the taste) – in 53 year old woman
- feeling of meteorism after long-term application - 1x
- intermittent joint and muscle pain - 1x

6. Laboratory analyses

In terms of the research samples were taken thrice to assess the basic biochemical properties (levels of urea, creatinin, bilirubin, cholesterol, ALT, AST, AMS in the blood) and the level of both general IgE in some

patients with the confirmed diagnosis of atopic hypersensitivity and the level of IgE in the patients with bronchial asthma. Spirometry was carried out to determine values of ventilatory functions. Laboratory analyses were made thrice, in particular:

1. Analyses on inclusion in the research
2. Analyses at the end of monitoring the condition of patients not using Enterogel (after 21 days as of the first analysis)
3. After using Enterogel (i.e. after 42 days as of the monitoring commencement on the whole or 21 days of using Enterogel).

The tables contain values of the analyses performed in all specified terms (20 patients) excluding patients with incomplete set of analyses.

Explanations:

M-male, F-female, K-control period, A – period of intensive treatment;

sIgE - specific IgE (patients with value of 0,2 showed no levels of specific IgE);

IgE (patients with value of 10 – showed no increased value of IgE level).

| | IgE-1K | IgE-2K | IgE-1A | IgE-2A | sIgE-1K | sIgE-2K | sIgE-1A | sIgE-2A |
|-----------|--------|--------|--------|--------|---------|---------|---------|---------|
| J.D,m,59 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| J.CH,ž,39 | 690 | 753 | 753 | 680 | 16,2 | 14,9 | 14,9 | 11,4 |
| H.T.,ž,61 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| V.H.,m,69 | 283 | 290 | 290 | 257 | 10,5 | 11,4 | 11,4 | 8,8 |
| N.L.ž,52 | 103 | 91 | 91 | 94 | 3,6 | 3,37 | 3,37 | 3,42 |
| B.K.m,67 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| D.B.ž,62 | 90,6 | 103 | 103 | 85 | 0,2 | 0,2 | 0,2 | 0,2 |
| L.P.,ž,33 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| E.S.,ž,47 | 10 | 10 | 10 | 10 | 0,77 | 0,77 | 0,77 | 1,54 |
| K.C.,m,22 | 1200 | 1200 | 1200 | 968 | 0,2 | 0,2 | 0,2 | 0,2 |
| Z,S,ž,47 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| D.N.,ž,56 | 80 | 80 | 80 | 90 | 0,2 | 0,2 | 0,2 | 0,2 |
| P.P.,m,26 | 178 | 178 | 178 | 178 | 0,2 | 0,2 | 0,2 | 0,2 |
| R.P.,m,26 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| V.K.,m,80 | 40 | 28 | 28 | 31 | 0,2 | 0,2 | 0,2 | 0,2 |
| M.N,m,11 | 10 | 10 | 10 | 10 | 0,2 | 0,2 | 0,2 | 0,2 |
| L.B,ž,27 | 1200 | 1200 | 1200 | 120 | 0,2 | 0,2 | 0,2 | 0,2 |
| M.J.,m,43 | 1200 | 1200 | 1200 | 1200 | 37 | 37 | 37 | 37 |
| O.B.,m,20 | 54 | 54 | 54 | 67 | 0,2 | 0,2 | 0,2 | 0,2 |
| R.M,ž,34 | 1200 | 1200 | 1200 | 1200 | 0,2 | 0,2 | 0,2 | 0,2 |

| ALT-1K | ALT-2K | ALT-1A | ALT-2A | AST-1K | AST-2K | AST-1A | AST-2A | AMS-1K | AMS-2K | AMS-1A | AMS-2A |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 0,38 | 0,35 | 0,35 | 0,76 | 0,3 | 0,35 | 0,35 | 0,56 | 0,79 | 0,79 | 0,79 | 0,84 |
| 0,75 | 0,84 | 0,84 | 0,77 | 0,77 | 1,13 | 1,13 | 0,77 | 0,73 | 0,82 | 0,82 | 0,59 |
| 0,32 | 0,33 | 0,33 | 0,38 | 0,42 | 0,46 | 0,46 | 0,47 | 0,94 | 0,96 | 0,96 | 0,98 |
| 0,81 | 0,37 | 0,37 | 0,4 | 0,46 | 0,37 | 0,37 | 0,4 | 0,75 | 0,74 | 0,74 | 0,88 |
| 0,32 | 0,31 | 0,31 | 0,29 | 0,36 | 0,31 | 0,31 | 0,29 | 1,46 | 1,28 | 1,28 | 1,6 |
| 0,4 | 0,46 | 0,46 | 0,44 | 0,43 | 0,52 | 0,52 | 0,49 | 1,2 | 1,19 | 1,19 | 1,14 |
| 0,27 | 0,24 | 0,24 | 0,2 | 0,48 | 0,52 | 0,52 | 0,46 | 1,29 | 1,12 | 1,12 | 1,31 |
| 0,46 | 0,88 | 0,88 | 0,82 | 0,45 | 0,67 | 0,67 | 0,66 | 0,88 | 0,88 | 0,88 | 0,84 |
| 0,31 | 0,31 | 0,31 | 0,32 | 0,32 | 0,32 | 0,32 | 0,29 | 0,27 | 0,27 | 0,27 | 0,26 |
| 0,3 | 0,33 | 0,33 | 0,29 | 0,48 | 0,37 | 0,37 | 0,42 | 0,28 | 0,31 | 0,31 | 0,33 |
| 0,37 | 0,62 | 0,62 | 0,22 | 0,38 | 0,52 | 0,52 | 0,33 | 0,98 | 0,74 | 0,74 | 0,82 |
| 0,3 | 0,36 | 0,36 | 0,33 | 0,35 | 0,37 | 0,37 | 0,39 | 0,85 | 0,77 | 0,77 | 0,84 |
| 0,94 | 0,93 | 0,93 | 0,93 | 0,53 | 0,49 | 0,49 | 0,49 | 1,19 | 1,1 | 1,1 | 1,1 |
| 0,38 | 0,38 | 0,38 | 0,38 | 0,28 | 0,28 | 0,28 | 0,28 | 1,01 | 1,01 | 1,01 | 1,01 |
| 0,45 | 0,45 | 0,45 | 0,45 | 0,55 | 0,55 | 0,55 | 0,5 | 0,74 | 0,74 | 0,74 | 1,02 |
| 0,24 | 0,24 | 0,24 | 0,28 | 0,47 | 0,47 | 0,47 | 0,42 | 1,55 | 1,55 | 1,55 | 1,5 |
| 0,37 | 0,37 | 0,37 | 0,37 | 0,4 | 0,4 | 0,4 | 0,4 | 0,77 | 0,77 | 0,77 | 0,77 |
| 0,38 | 0,38 | 0,38 | 0,38 | 0,35 | 0,35 | 0,35 | 0,35 | 0,67 | 0,67 | 0,67 | 0,67 |
| 0,47 | 0,47 | 0,47 | 0,47 | 0,71 | 0,71 | 0,71 | 0,71 | 1,42 | 1,42 | 1,42 | 1,42 |
| 0,3 | 0,3 | 0,3 | 0,3 | 0,35 | 0,35 | 0,35 | 0,35 | 0,8 | 0,8 | 0,8 | 0,8 |

The annex to this concluding statement contains statistical assessment. Statistical assessment evidences absence of statistically significant changes between individual analyses in relation to the properties examined. The absence of statistically significant changes in the monitored properties can be explained on one hand by the fact that basic biochemical values in all the patients were within the limits of usual referential normality. As regarding the values of general IgE and specific IgE, the 21-day period is evidently too short a period to reflect a possible dynamics of changes in them.

Conclusion

In 2009 there was carried out an experimental monitored research of the influence of enterosorbent ENTEROSGEL on the clinical condition and some aspects of laboratory analyses of patients with allergic diseases (bronchial asthma, atopic eczema, chronic hives) as well as in relation to some immune pathological conditions (chronic fatigue syndrome, polyvalent and food allergy, chronic keratit and uveit). It was determined that

- the drug is of a high tolerability, treatment cessation after 3 days happened only to one 53-year-old woman for the reason of occurrence of nausea and vomiting, recurring also after the treatment cessation and change of the product's taste.
- One 7-year-old girl found the medical product not tasty which did not constitute a reason to suspend or cease the researches
- 74% of the patients noticed improvement in their health condition which manifested itself on the whole as a feeling of health improvement mainly induced by digestion improvement, removal of digestive disorders, normalization of stool (35%), improvement in the itching condition, hives (17%), sleep improvement (13%), reduction or suspension of fatigue (13%) as well as reduction in intensity of some other allergic manifestations
- Statistically significant improvement in the examined symptoms were noticed for bronchial asthma, chronic hives and other examined immune pathological conditions (polyvalent and food allergy, chronic fatigue syndrome)
- No statistically significant influence on the patients with atopic eczema was noticed
- no statistically significant changes in laboratory values (general IgE, specific IgE, urea, creatinin, bilirubin, cholesterol, AST, ALT, AMS) were noticed.

As a conclusion it should be specified that the medical agent ENTEROSGEL influences favorably mainly the health condition of such patients which in terms of the main disease also suffer from digestive disorders, stool frequency, abdominal distention, digestive system discomfort, which in their turn influence the basic examined disease (bronchial asthma, chronic hives, chronic fatigue syndrome, food allergies) and can be recommended as rather a well-timed medical agent in terms of integrated treatment of allergic diseases.

December 17, 2009 in the town of Olomoutz

The statement is prepared by: Associate Professor, MD Jaromír Bystron, candidate of medical sciences)