



PRESTO  GEL

Natural lasting relief for inflamed Haemorrhoids

PRESTO GEL – CLINICAL REPORT

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Clinical Report
About Presto Gel Effectiveness Examining and
Conclusions Treatment against Hemorrhoids

during severe attacks

The research was carried out in the Israpharm Clinic, 55 Ha-Histadrut St., Beer-Sheva Israel

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Briefly about Hemorrhoids

Hemorrhoids are large and / or very painful clusters of blood vessels located in the rectal area.

Hemorrhoids are very common in industrialized countries. Usually the first symptoms may appear in the early 20's of a person's life, but these symptoms are not clear until the 40's. According to some estimations about 70% of the population from their 50's onwards suffer to a certain extent from symptomatic Hemorrhoids. Females suffer from Hemorrhoids more frequently than males. One of the assumptions is that pregnancy and delivery produce increased pressure on the rectal and anal areas. Hemorrhoids are divided in two main groups: external (A bulge on the side of anus) and internal (in the lower part of the rectum). Many patients suffer from pain caused by anal fissure which in turn is caused by Hemorrhoids.

Factors that cause Hemorrhoids: There is an intricate system of veins in the rectal and anal areas that are supposed to drain blood from the area. The factors increasing vein congestion are usually those increasing the pressure, such as increased intra-abdominal pressure, exertion during defecation or prolonged sitting may also accelerate the formation of Hemorrhoids.

Increased intra-abdominal pressure can be caused by the following factors:

1. Exertion during defecation usually caused by constipation.
2. Pregnancy – blood volume increases, while Progesterone weakens muscles, the uterus is heavy and there is pressure on the lower vena cava while lying on the back.
3. Portal hypertension, drain the Hemorrhoids and can be caused by cirrhosis.
4. Coughing and vomiting increase intra-abdominal pressure producing pressure on veins where the blood pressure is usually very low - stopping the flow.
5. Strenuous physical activity.
6. Psychological stress can also awaken Hemorrhoids.
7. Severe cardiac insufficiency can worsen Hemorrhoids because of blood vessels' problems and problems in venous blood drainage.

The four phases of Hemorrhoids are:

1. Internal Hemorrhoids – which are not felt
2. Coming out during defecation and retracting unaided.
3. Coming out and not retracting, have to be thrust inside.
4. Those that come out and cannot be returned.

- **Each phase can be accompanied with bleeding - pain appears especially in the last phase.**

Internal Hemorrhoids form above the anal-rectal line. Sometimes internal Hemorrhoids may grow to a degree till they pass the vein which is under the Anal Sphincter.

Research reason and motives

A lot of people who suffer from Hemorrhoids turn to us frequently in search for alternative solutions to minimize their pain and suffering, as they have no hope with the types of treatment available today, such as:

- a. Most of the medicinal ointments whose use is limited to short periods owing to certain ingredients concerning which there are specific warnings, the patient is forced to stop the treatment prior to any improvement occurring in his/her condition.
- b. Waiting for treatments involving surgical intervention is a time-consuming process.
- c. An additional reason is the tendency to avoid giving treatment in certain cases for fear of drug interactions and occasionally also because of women's pregnancies.

Research goals

To develop a preparation based of natural ingredients that meets the following requirements:

- a. Allows unlimited duration of use.
- b. Is devoid of side effects.
- c. May be used by pregnant and postnatal women.
- d. May be used by both men and women of all ages, in whatever situation, without contradicting other medications or arousing inter-medicinal reactions
- e. Acts fast and efficiently in relieving and alleviating local pain and pressure and has a significant disinfection ability against bacterial infections which cause inflammation in the rectal area.

Method of Research

In the third experimental phase of the research which was conducted over a period of 6 months, between 1/11/2006 – 30/4/2007 (see research booklet), to examine the clinical effectiveness of the preparation "Presto Gel", 120 patients were chosen at random from among those who had come to our clinic for treatment against Hemorrhoids during the same period. They were divided into 4 groups. Each group consisted of 30 patients at various stages of the illness.

For purposes of comparison as against other preparations, the experimental results were examined regarding 30 out of 61 participants in the third phase of the general research.

Each of the 4 groups was treated with a different preparation:

- Group 1: Was treated with the "Presto Gel" preparation which contains natural ingredients (Water, Aloe Barbadensis Extract, Triethanolamine, Carbomer, Geranium Thunbergii Extract, Pogostemon CablinLeaf Extract).
- Group 2: Was treated with the preparation named "A" (for research purposes), which contains Ethyl-three-O-benzyl-D-glucofurolyzyl 3,5,6 and Benzocaine
- Group 3: Was treated with the preparation named "B" (for research purposes), which contains Benzocaine, Hydrocortisone, and Zinc.
- Group 4: Was treated with the preparation named "C" (for research purposes), which contains Nifidipine, Benzocaine.

Each patient in all of the four groups was under treatment and follow-up for 60 days.

Analysis:

1. Table No. 1 demonstrates the dynamics of the symptoms in all of the treatment groups of this article.
2. Table No. 2 demonstrates the level of analgesic effectiveness of all the preparations in all phases of the illness in all of the treatment groups according to the criteria of speed and duration of the effect and a subjective grading of the strength of the analgesic effect.

Diagram No. 1: Breakdown in percentages according to degree of illness in all patients participating in the research.

Participation in the research: 120 Hemorrhoids patients.

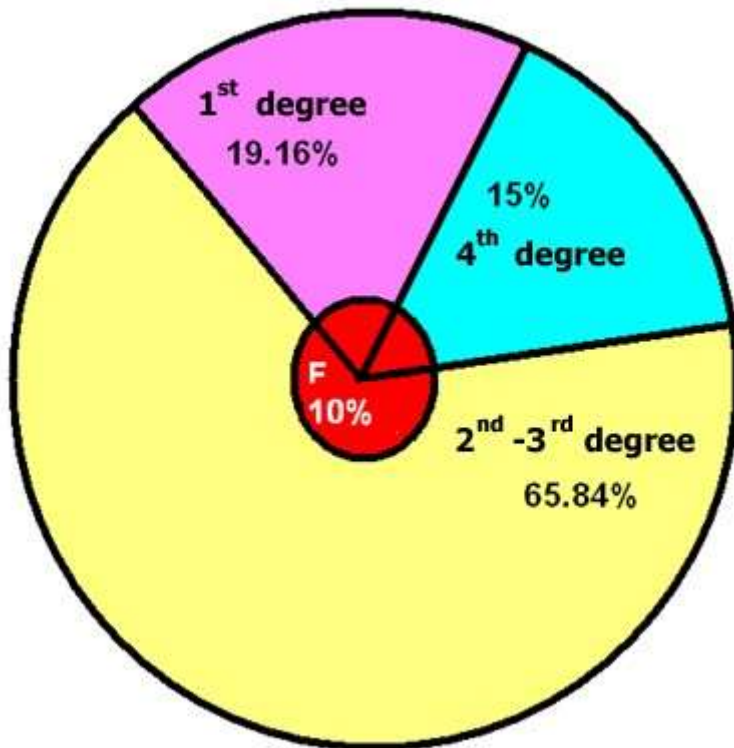
Women: 63 (52.5%)

Men: 57 (47.5%)

Aged: 24-68 years.

Hemorrhoids 1st degree: 23 patients (19.16%)
2nd-3rd degree: 79 patients (65.84%)
4th degree: 18 patients (15%)

With fissure (F) comprising all 4 degrees: 12 patients (10%)



General Anamnesis: From 1 month to 5 years.

Hemorrhoidectomy: among 7 patients (5.83%)

After ligature: 18 patients (15%)

After sclerotherapy: 12 patients (10%)

First time: 19 patients (15.83%)

Used other preparations in the past: 104 patients (86.67%)

Other accompanying illnesses: among 53 patients (44.17%)

Treatment during pregnancy and nursing: 4 patients (3.34%)

Diagram No. 2: Breakdown in percentages according to degree of illness in patients treated with Presto Gel.

Participation in the Group: 30 Hemorrhoids patients (Group No. 1)

Women: 19 (63.34%)

Men: 11 (36.66%)

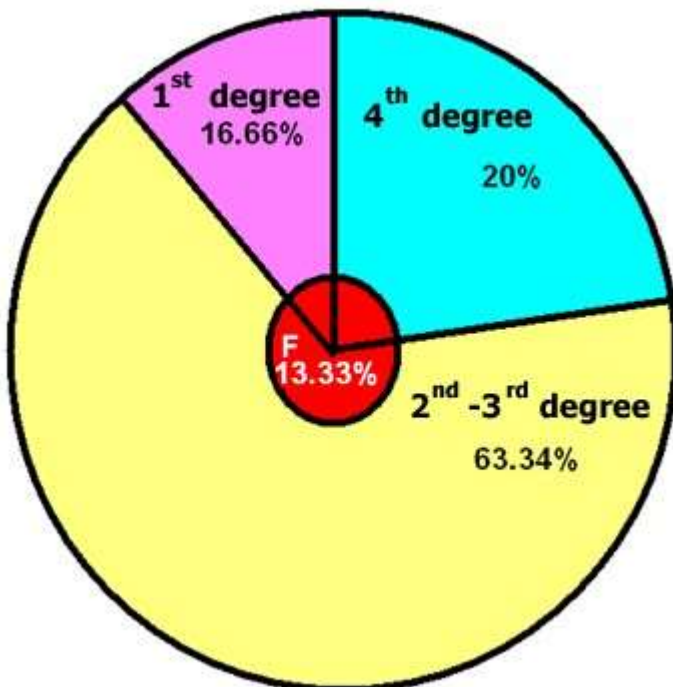
Aged: 24-68 years.

Hemorrhoids 1st degree: 5 patients (16.66%)

2nd-3rd degree: 19 patients (63.34%)

4th degree: 6 patients (20%)

With fissure (F) comprising all 4 degrees: 4 patients (13.33%)



General Anamnesis: From 1 month to 5 years.

Hemorrhoidectomy: among 2 patients (6.64%)

After ligature: 5 patients (16.66%)

After sclerotherapy: 4 patients (13.34%)

First time: 5 patients (16.67%)

Used other preparations in the past: 25 patients (83.34%)

Other accompanying illnesses: among 11 patients (36.67%)

Treatment during pregnancy and nursing: 4 patients (13.33%)

Diagram No. 3: Breakdown in percentages according to degree of illness in patients treated with preparations “A”, “B” and “C” (as called for research purposes).

With the participation of three groups: Group No. 2, Group No. 3 and Group No. 4 (a total of 90 Hemorrhoids patients)

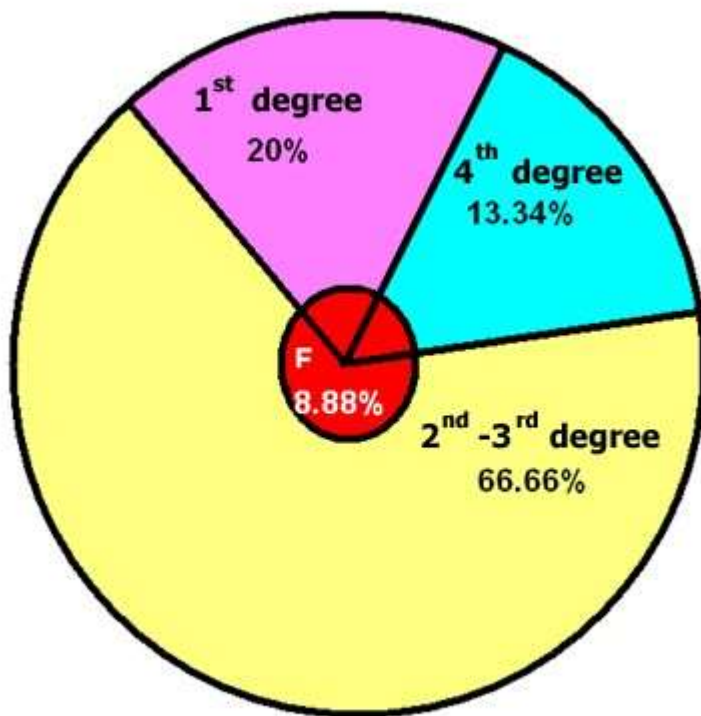
Women: 44 (48.89%)

Men: 46 (51.11%)

Aged: 24-68 years.

Hemorrhoids 1st degree: 18 patients (20%)
2nd-3rd degree: 60 patients (66.66%)
4th degree: 12 patients (13.34%)

With fissure (F) comprising all 4 degrees: 8 patients (8.88%)



General Anamnesis: From 1 month to 5 years.

Hemorrhoidectomy: among 5 patients (5.55%)

After ligature: 13 patients (14.44%)

After sclerotherapy: 8 patients (8.88%)

First time: 14 patients (15.55%)

Use of other preparations in the past: 79 patients (87.77%)

Other accompanying illnesses: among 42 patients (46.66%)

Treatment during pregnancy and nursing: 0 patients (0%)

Table No. 1: Dynamics of the symptoms of hemorrhoids in all groups treated during the research

For purposes of Analysis, 3 symptoms typical of a severe attack of Hemorrhoids were examined:

1. Pain and feeling of pressure in the anus.
2. Rectal bleeding during defecation.
3. Objective signs (edema, swelling, reddening, and inflammation).

The Condition Before Beginning Treatment:

Symptom 1 - Exists with all those treated from all groups – 100%

Symptom 2 - Exists with those treated with Presto Gel – 12 patients.

“ Exists with those treated with preparation "A" – 14 patients.

“ Exists with those treated with preparation "B" – 12 patients.

“ Exists with those treated with preparation "C" – 11 patients.

Symptom 3 - Exists with all those treated from all groups.

Symptoms	Day of Treatment	Number of patients with a symptom			
		Presto Gel	Preparation "A"	Preparation "B"	Preparation "C"
<u>Symptom 1</u> Pain and feeling of pressure in the anus	Before starting treatment	30	30	30	30
	day 1	3	26	28	25
	day 7	1	23	25	20
	day 14	0	18	—	15
	day 28	0	—	—	—
	day 60	0	—	—	—
<u>Symptom 2</u> Rectal bleeding during defecation	Before starting treatment	12	14	12	11
	day 1	12	14	12	11
	day 7	10	13	12	10
	day 14	7	10	—	8
	day 28	2	—	—	—
	day 60	0	—	—	—
<u>Symptom 3</u> Objective signs (edema, swelling, reddening, and inflammation)	Before starting treatment	30	30	30	30
	day 1	30	30	30	30
	day 7	25	27	29	26
	day 14	13	24	—	22
	day 28	7	—	—	—
	day 60	2	—	—	—

(—) Treatment stopped due to restrictions on use of preparation.

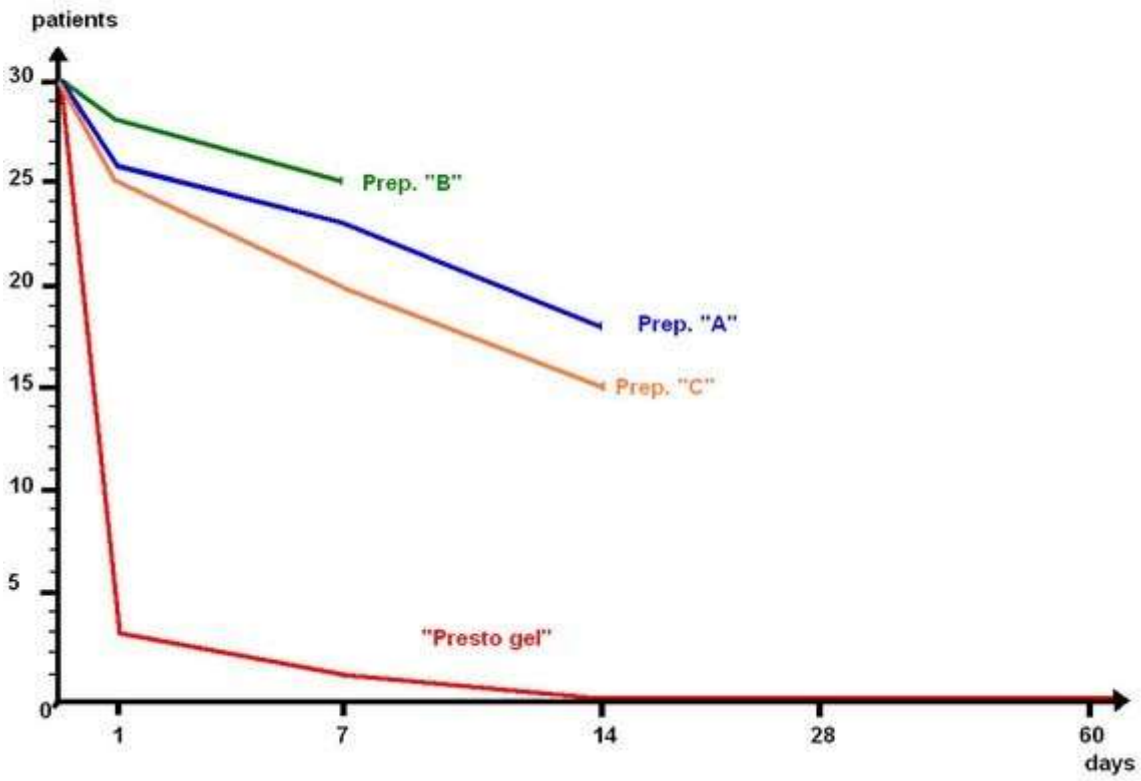
In the group treated with Presto Gel, most of the patients reported significant relief of pain and pressure already on the first day of treatment.

In the groups treated with preparations “A” and “C” the treatment was stopped after two weeks because of restrictions on the period of use.

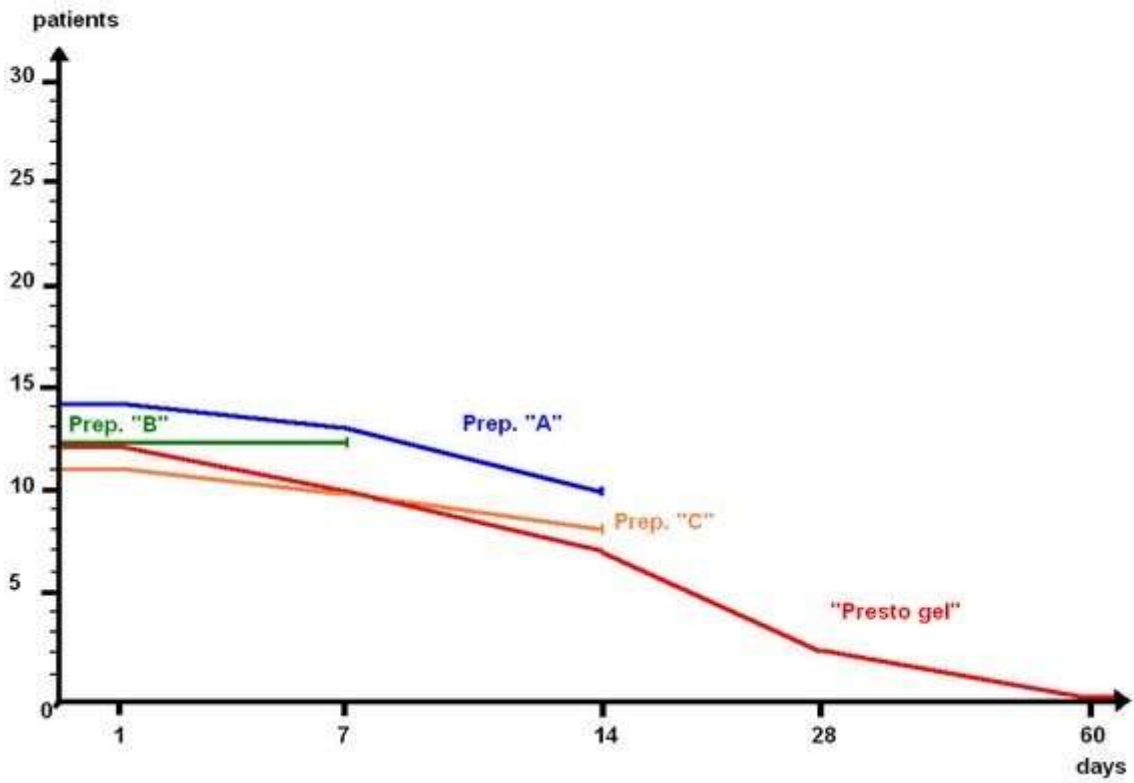
In the group that was treated with preparation “B” the treatment was stopped after one week because of restrictions on the period of use.

Among all the patients from all the groups treated with Presto Gel throughout the entire clinical examination period (6 months) there were no significant side effects from the use of Presto Gel, except in two cases where a slight burning sensation was felt immediately after application and this being due to the strong disinfecting effect of the gel, which lasted between 2-5 minutes after each application. By continuing the treatment the burning sensation completely disappeared (in an individual manner) during the first 1-4 days of the treatment.

Graph No. 1. Dynamics of pain in the anus in all groups.



Graph No. 2. Dynamics of rectal bleeding in all groups.



Graph No. 3. Dynamics of objective signs in all groups.

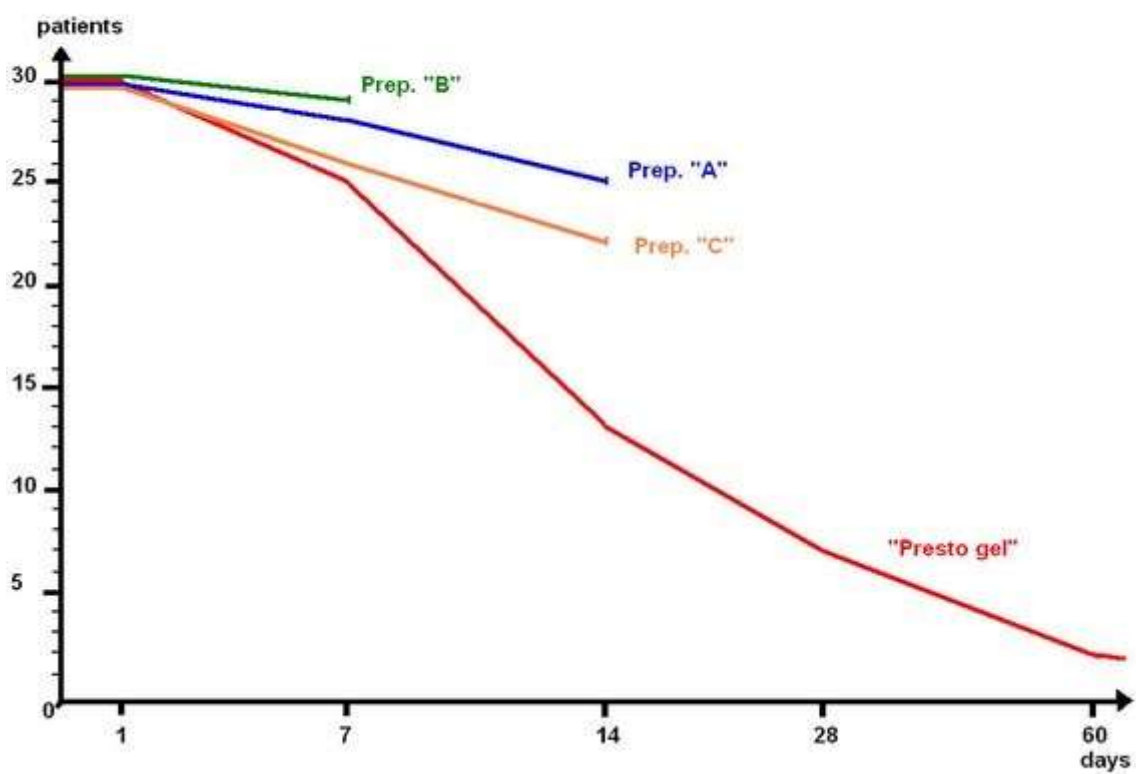


Table No. 2. The level of analgesic effectiveness (by measure of speed, duration and strength) in all groups.

Groups Criteria	Hemorrhoids 1 st degree				Hemorrhoids 2 nd degree				Hemorrhoids 3 rd degree				Hemorrhoids 4 th degree			
	P.G	A	B	C	P.G	A	B	C	P.G	A	B	C	P.G	A	B	C
Speed of appearance of the analgesic effect (minutes)	1-2	10-15	10-15	10-15	1-2	10-15	10-15	1-2	10-15	10-15	1-2	10-15	10-15	1-2	10-15	10-15
Duration of the analgesic effect (minutes)	2-5 hrs	15-30 min	15-20 min	20-40 min	2-5 hrs	15-30 min	10-20 min	20-40 min	2-5 hrs	15-30 min	10-20 min	20-40 min	2-5 hrs	15-30 min	10-20 min	20-40 min
Subjective grading of the strength of analgesic effect (from 1 to 10)	9-10	0-2	0-1	0-2	9-10	0-1	0-1	0-2	8-10	0-1	0-1	0-1	8-10	0-1	0-1	0-1

Table No. 3. Comparison according to criteria

Criteria	Presto Gel	Preparation “A”	Preparation “B”	Preparation “C”
Natural product	Yes	No	No	No
Side effects	No	Yes	Yes	Yes
Fast and strong analgesic effect	Yes	No	No	No
Duration of analgesic effect from 2 to 5 hrs	Yes	No	No	No
Disinfection effect	Yes	No	No	No
Anti-inflammatory effect	Yes	Yes	Yes	No
Astringent effect	Yes	Yes	Yes	Yes
Healing effect (Regeneration)	Yes	No	Yes	No
Contra-indication	No	Yes	Yes	Yes
May be used during pregnancy and nursing	Yes	No	No	No
Restriction on frequency of daily use	No	Yes	Yes	Yes
Restriction on duration of treatment	No	Yes	Yes	Yes
May be used as a preventive treatment	Yes	No	No	No
Physician's prescription required	No	Yes	Yes	Yes

Summary of Research

The results of the clinical research show unequivocally that the preparation “Presto Gel”, which contains natural ingredients, acts in an extraordinary way as the most effective means of treatment in severe attacks of Hemorrhoids. Its analgesic (pain relieving) activity is stronger, faster and longer-lasting in comparison with other preparations used in the research.

Together with this, the astringent and anti-inflammatory actions are more effective and the healing ability of the fissure in the anus is far better than those of the other preparations.

Since Presto Gel is free of side effects, it is possible to use it with no restrictions (i.e. more frequently and for a long period), a necessary condition for the treatment of severe attacks of Hemorrhoids.

Presto Gel brings significant relief, amazingly fast from the great suffering caused by Hemorrhoids.

It is certainly possible to use it as preventive treatment. The preparation is suitable for use by men and women of all ages, pregnant and nursing women, and people who take prescription medicines simultaneously for the treatment of various illnesses, with no contra-indications.