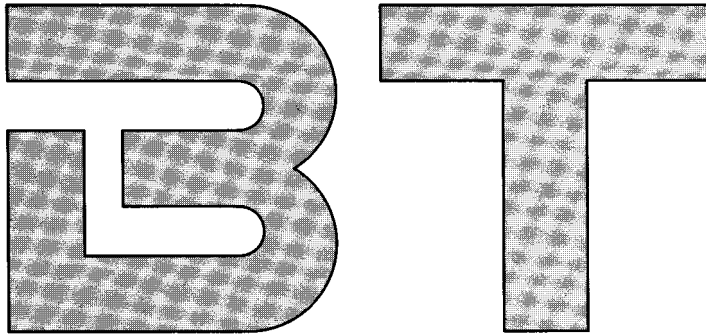


# BIOLOGICAL THERAPY

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## **Experience with a Homeopathic Suppository Preparation in the Medical Practice**

by S. Zenner and H. Metelmann

# Experience with a Homeopathic Suppository Preparation in the Medical Practice

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The Viburcol® suppository for infants and children is a homeopathic preparation applied in treatment of both febrile and non-febrile conditions of restlessness, pain (due to teething, abdominal cramps such as flatulent colic, etc.), as well as in symptomatic therapy of influenza infection. The components of this medication include chamomilla (*German camomile*), belladonna (*deadly nightshade*), dulcamara (*bittersweet*), plantago major (*plantain*), pulsatilla (*pasqueflower*), and calcium carbonicum Hahnemanni (*Hahnemann's calcium carbonate*).

## Camomile and Belladonna as Chief Constituents

These indications have been determined through homeopathic drug proving carried out with the preparation's individual constituents. The homeopathic substance chamomilla primarily affects the nervous system(3). This medicament is particularly appropriate as a sedative in treatment of conditions of nervous agitation(5). Further disorders within the symptom complex of camomile include abdominal cramps, flatulent colic, odontoneuralgia, and dentio difficilis(3). Belladonna's symptom picture is characterized by high fever, abnormally warm skin, and accelerated pulse (7), thus constituting an agent well suited to therapy of acute febrile infectious disorders. The remaining constituents serve to supplement the preparation's spectrum of efficacy.

## Reports on Utilization in the Medical Practice

Multiple accounts regarding the therapeutic results of Viburcol have been published to date, including the 1986 study conducted by H. Ries, in which 44 children were treated by means of this preparation for influenza infection(6). The series of publications was supplemented through additional reports on experience with Viburcol in the medical practice (1, 2, and 4).

In collaboration with numerous physicians, the present surveillance study was composed with the purpose of documenting this preparation's methods of application pertaining to the entire range of indications, as well as the therapeutic results thereby achieved. A further goal was the detection and registration of any undesirable medicinal effects.

## Procedure

Data was obtained by means of a standardized questionnaire, which was distributed among the participating physicians to these ends. In reply to a series of specific questions, all relevant patient and therapeutic information was entered onto one such questionnaire per individual case. Here, in addition to each patient's age and sex, a description of the diagnosis as well as the previous term of illness was documented. As the study was to precisely reflect the entire patient collective treated with this preparation, no criteria were stipulated concerning the exclusion or inclusion of certain groups of the patient population to be documented.

The recommended dosage consisted of 2 to 3 suppositories daily; deviation from this amount was acceptable, providing corresponding notation was made. Unrestricted application of further therapeutic measures was also permitted in treatment of individual cases in which the attending physician deemed such to be advisable. Categorized as either "simultaneously-prescribed adjunctive medication" or "non-medicinal therapy (physiotherapy, etc.)", such supplementary measures were recorded under the appropriate rubric of the questionnaire. Therapeutic results were to be assessed by the physician according to a scale of "very good, good, satisfactory, no improvement (i.e. symptoms unchanged), and worsened"; any undesirable medicinal effects observed

were to be recorded in the evaluator's own words.

A total of 221 physicians of various fields participated in this study, the largest contingent consisting of pediatricians (59.3 %) and general practitioners (28.1 %). In the aggregate, 3083 questionnaires were completed and returned by these medical professionals.

## Information and Data Processing

The informational material was registered and processed by means of an appropriate computer program. Of the total 3083 questionnaires, 74 contained neither data concerning diagnoses nor therapeutic results. As examination of these forms also failed to reveal any comments or indication of undesirable medicinal effects, they were subsequently disregarded in the further evaluation process.

On the basis of the diagnosis information provided within the free-text section, the patients were categorized into five groups, whereby the following procedure was applied in cases of multiple symptoms: All patients for whom infection was reported were assigned to Group I, entitled "infectious disorders": while those displaying "intestinal cramps" were entered under Group III. The next priority among the remaining patients were those indicated as suffering from pain (Group IV: "conditions of pain"), ensued by "states of nervous restlessness" (Group II). The patient collective then remaining unclassified was registered under Group V ("miscellaneous diagnoses").

## Description of the Patient Collective

Viburcol, the subject of this study, was administered in therapy of a total of 3009 patients. 1427, or 47.4 percent of these were identified as female, 1534 as male (51.09%), and in 48 of the cases (1.6%), no reference to the patient's sex was recorded. The average age within

this collective measured 18 months, whereby the majority of patients was aged less than one year, an age-related concentration of patients also observed within each of the individual diagnostic categories. Divided according to sex, the graph in Figure 1 illustrates the age distribution among the patients documented.

With 72.2 %, or 2173 of the cases, the diagnosis most frequently indicated was that of "infectious disorders": ensued in order of decreasing number by "states of nervous restlessness" (341 cases, or 11.3 %), "conditions of pain" in 291 cases (9.7 %), "intestinal cramps" (127 cases, or 4.2910), and "miscellaneous diagnoses", indicated in 2s percent, or 77 instances.

The average period entered under "term of diagnosis" measured three days. Indications of the previous duration of illness and / or complaints, however, varied substantially among the various diagnostic groups. For example, in 50% of the patients, conditions of nervous restlessness and intestinal cramps had persisted for a period in excess of 14 days prior to seeking medical advice, with an equal percentage previously suffering from painful conditions for more than 10 days. 75 % of the patients displaying influenza infection, on the other hand, appeared for treatment within the initial 6 days of affection.

#### Medication

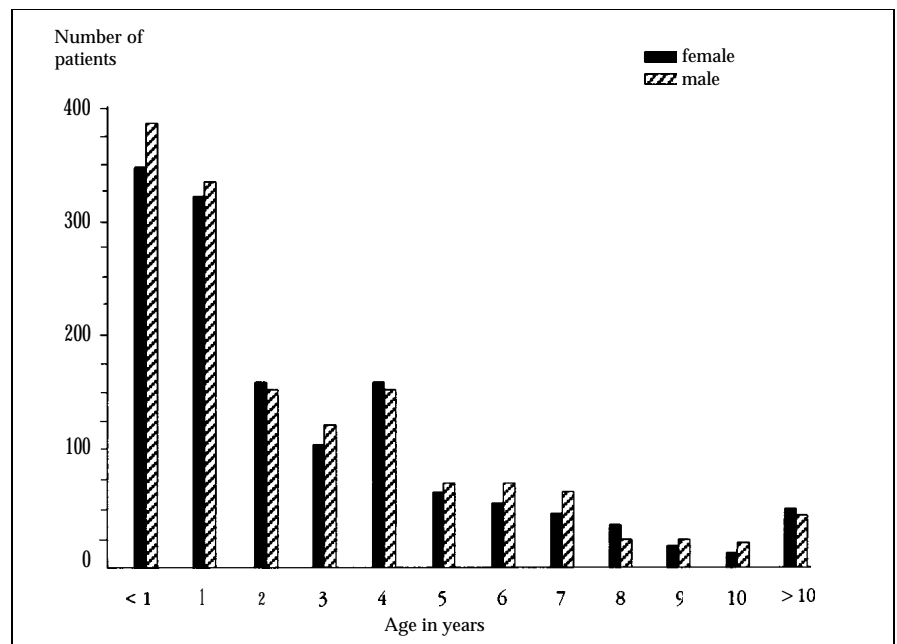
From a total of 3009 patients, 2146 of these received the target preparation at a dosage of 2 to 3 suppositories daily; corresponding to 71.3 %, this represents the most frequently-prescribed dosage. Noticeable is the dosage received by the patients suffering from infectious disorders, which is generally higher than that among the remaining diagnostic classifications. Refer to Table 1.

Duration of therapy until safe discontinuation of medication measured less than one week in 56.590 of the cases (based on the entire collective); for 38.2 % of the patients, treatment was carried out during a time span of one week to one month. A period of treatment in excess of one month was indicated in 3.8 percent of the cases. The

therapeutic terms of greatest brevity were observed in the group "infectious disorders" (65.1% completed within seven days), whereas the remaining diagnostic classifications required more lengthy spans of treatment (Table 1).

Utilizing the preparation under examination, monotherapy was performed in 1413 cases (47.0%); 1515 patients, or 50.3%, received supplementary medication. The highest percentage of patients for whom additional medica-

**Figure 1**  
*Distribution of Patient Collective in Regard to Age and Sex*



**Table 1**  
*Therapeutic Data on 3009 Treated Patients*

	Total Collective	Group I (Infectious Disorders)	Group II (States of nervous restlessness)	Group III (Intestinal cramps)	Group IV (Conditions of pain)	Group V (Misc. Diagnoses)
	n = 3009	n = 2173	n = 341	n = 127	n = 291	n = 77
<i>Dosage</i>						
2 supp. or less daily	10.0 %	9.3 %	10.3 %	9.4 %	15.8 %	6.5 %
3 supp. or less daily	71.3 %	75.5 %	50.4 %	69.3 %	64.6 %	74.0 %
over 3 supp. daily	5.0 %	6.4 %	1.2 %	0.0 %	1.7 %	2.6 %
<i>Duration of therapy</i>						
less than 1 week	56.5 %	65.1 %	30.2 %	37.0 %	30.2 %	62.3 %
1 week -1 month	38.2 %	31.9 %	57.8 %	41.7940	61.9 %	31.2 %
over 1 month	3.8 %	1.9 %	10.0 %	14.2 %	5.2 %	6.5 %
<i>Simultaneously-prescribed adjunctive medication</i>						
	50.3940	61.0 %	14.4 %	37.8 %	25.8 %	22.1 %
<i>Additional therapeutic forms</i>						
	29.1 %	36.3 %	6.5 %	27.6 %	5.5 %	18.2 %

Table 2:  
*Modes of Concomitant Medicinal Therapy Applied in Excess of 1% of Surveilled Cases*

Type of medication administered	No. of cases
Analgesics	58
Anti-allergic agents	8
Antibiotic/Chemotherapeutic drugs	122
Anti-emetic/Anti-vertigo agents	7
Antipileptics	5
Antimycotics	18
Antiphlogistics	152
Antitussive agents/Expectorants	478
Balneotherapeutics	5
Bronchospasmolytic/Antiasthmatic remedies	17
Corticoid drugs	5
Dermatics	33
Influenza remedies	138
Somnifacient agents/Sedatives	5
Gastro-enteric medications	138
Mineral preparations	9
Stomato-pharyngeal therapeutic agents	46
Ophthalmic	11
Otologic preparations	91
Rhinologic medications	376
Spasmolytic agents	6
Sulfa drugs	21
Akerants/Preparations for immune stimulation	136
urologic medications	7
Vitamins	21
Material for wound treatment	4
Preparation in series/Homeopathic agents	399

tion was simultaneously prescribed (61.0%) occurred within the group displaying infectious disorders, with the lowest (14.4%) registered among the patients suffering from nervous restlessness. A summary of the most significant modes of concomitant medicinal therapy is provided in Table 2.

Supplementary, non-medicinal measures were applied in 875 cases (Table 3).

### Therapeutic Results

Calculated on the basis of the total patient collective (n=3009), the therapeutic results were assessed as "very good" or "good" in 82.7910 of the cases. An additional 12.2% of the resultants received the rating "satisfactory". Consequently, therapeutic success was achieved in a total of 94.9% of all cases studied. 4.6% of the patients failed to show improvement, and a worsening in condition was observed to temporarily occur in 0.5% of the cases.

Figure 2 graphically illustrates the results achieved through treatment, as expressed in percentage values. The diagnostic group receiving the highest percentage (86.5%) of "very good / good" ratings in evaluation of therapeutic success was that of infectious disorders.

### The Influence of Concomitant Therapy

Under monotherapy employing the target preparation, the results were assessed as "very good" or "good" in 82.3% of the cases; under prescription of concomitant medication, this value measured 83.2%. Supplementary therapy of a non-medicinal character achieved either "very good" or "good" results in 86.3% of all cases, and 81.6% were thus evaluated without application of additional therapeutic measures.

The therapeutic results in correlation with diagnoses and forms of supplementary treatment are portrayed in Table 4. The influences exerted by each type of concomitant therapy, medicinal as well as non-medicinal, have been presented here independently of one another. Study of this table reveals the diagnostic groups "infectious disorders" and "nervous restlessness" to show no appreciable difference among those patients having received supplementary medication, and those to whom exclusively the target preparation was administered. Moreover, the percentage of therapeutic success among those patients suffering from intestinal cramps, conditions of pain, as well as under "miscellaneous diagnoses" registered lower upon application of concomitant medication than through administration of Viburcol alone. The authors hypothesize this to be a consequence

Figure 2  
*Percentile Distribution of Therapeutic Results Attained in Patients Treated (n = 3009)*

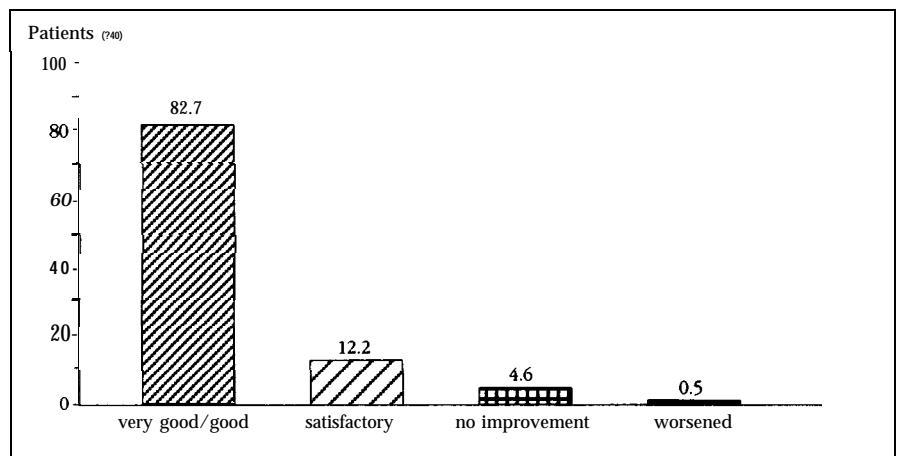


Table 3  
*Modes of Non-Medicinal Concomitant Therapy, Applied in Excess of 0.1% of Surveilled Cases*

Type of therapy	No. of cases
Balneotherapy	31
Radiotherapy	15
Dietary regimen	25
Hydrotherapy	4
Anapnotherapy	45
Massage	18
Physiotherapy	9
Compresses/Wraps/Fomentation	670
Psychotherapy	8

of patient selection, as those receiving additional medication generally displayed a more serious symptom complex than those who did not, and thus the percentage rate for therapeutic success lay innately at a correspondingly lower level.

Within the collective as a whole, as well as in the diagnostic classifications "infectious disorders", "nervous restlessness": and "conditions of pain", the application of supplementary, non-medication therapy achieved a higher percentage of "very good" or "good" results than did exclusively medicinal treatment without concomitant therapy.

#### Undesirable Medicinal Effects

From a total of 3083 questionnaires, 19 bore affirmative replies to the inquiry regarding undesirable medicinal effects. Loose stools or diarrhea was described in 9 cases; two further patients reported a burning sensation or pain subsequent to suppository insertion. Local dermal reactions in the anal vicinity were described in three patients, as were one case each of slight constipation, and extreme restlessness. A rash occurred in one instance, whether this exanthem was due to allergy remained unclarified; and two patients indicated experiencing nausea.

The casual relationship existing between administration of medication and the reported negative effects, however, is more or less dubious in every instance. Not a single case was documented in which, ensuing a withdrawal trial, re-exposition had incurred repetition of the same manifestations. In all likelihood, a portion of the described irregularities constituted symptoms of the primary disease in point (for example diarrhea as a symptom of an infectious disorder); a further possibility being their development as a consequence of unadroit suppository insertion.

#### Discussion

Falling within the field of post-marketing drug surveillance, applicational studies have long constituted a reliable instrument for determining the physicians' therapeutic conduct in regard to a specific medication, as well as for re-evaluation of this medicament's

tolerance. These studies are particularly appropriate for documenting the serviceability of a preparation under actual practice conditions. Due to the multiplicity of cases reported, as well as to the high number of participating physicians, effects conceivably promoting misrepresentation have been extensively neutralized. Such factors include statistic fluctuation within the ascertained data, as well as any falsification of findings due to subjective attitudes the prescribing physicians may harbor toward the target preparation. Without due reservation, however, the results obtained through applicational studies are not to be equaled with the findings of clinical testing, in which solely the therapeutic agent is subjected to examination. In the former instance, the evaluation of therapeutic success is not limited to the medicinal effect alone, but also reflects the spontaneous development of the disease in treatment, as well as the results of any concomitant therapy.

In the present application surveillance report, patients suffering from infectious disorders formed the major contingency within the collective treated, a percentage of 72.2 %. In 86.5% of the cases within this group, therapy was assessed as "very good" or "good", thus achieving a higher rating than did the collective as a whole (82.790). Grounds for this outcome conceivably lie in the fact that these patients received higher dosages of the surveyed preparation than did the members of other diagnostic groups; a further, partial explanation may consist of these results, constituting a natural parallel to the course of the disorders monitored.

Within the remaining diagnostic classifications (nervous restlessness, intestinal cramps, painful conditions, and miscellaneous diagnoses), the percentage of therapeutic success assessed with a minimum of "good" measured between 66.1% and 84.590, whereas the corresponding percentage of therapeutic failure reached 10.6% in the least favorable instance (calculated on the basis of the total number of cases within the individual groups). The patients of these four diagnostic groups generally received Viburcol in lower dosages than

was administered to those with infectious disorders; however, treatment within the former classifications was generally applied over a longer period of time.

#### Therapeutic Success Achieved in Over 90% of all Cases

Viewed in reference to the entire patient collective processed (including those cases in which supplementary therapy was applied), calculation of therapeutic success totalled 94.9%.

50.3% of the surveyed patients received medicinal agents in addition to the preparation under examination. Here, evaluation of therapeutic success and its degree of dependency upon the application of the target preparation constitutes a more complex undertaking than in those cases in which treatment consisted of monotherapy, administering Viburcol alone. Comparison of the therapeutic success ratings among patients with and without supplementary medication (Table 4), however, makes the following evident: the positive results achieved, as documented in this applicational study, are by no means ascribable to adjuvant therapy alone.

#### Viburcol Well Tolerated

For years, the suppository preparation under observation has been known for its excellent tolerance, a characteristic which has been confirmed in the present applicational study. The few undesirable effects reported unanimously consisted of disorders of a minor, temporary nature. Moreover, an eventual causal relationship existing between application of the preparation and the manifestations described is unsubstantiated.

The overwhelming positive evaluations submitted by a multiplicity of physicians, in regard to tolerance and efficacy of the examined suppository preparation, has confirmed the experiences recorded in a number of previous publications (1,2,4,6). Thus this preparation meets all demands for an effective, yet virtually risk-free therapy of febrile, as well as non-febrile restlessness, influenza infection, and aches and pain, in both infants as well as in larger children.

**Table 4**

*Therapeutic Results Achieved Through the Suppository Preparation Under Surveillance in Interdependency with Mechanical and Non-mechanical Adjuvant Therapy.*

	Group I Infectious Disorders)	Group II States of nervous restlessness)	Group III (Intestinal cramps)	Group IV (Conditions of pain)	Group V Misc. Diagnoses)	Total Collective
	n = 2173	n = 341	n = 127	n = 291	n = 77	n = 3009
<i>Without additional medication</i> (n= 1413)						
very good and good	37.6 %	72.1 %	68.4 %	79.8 %	38.4 %	82.3 %
satisfactory	8.8 %	17.7 %	25.0 %	16.0 %	8.3 %	12.5 %
unsuccessful or worsened	3.6 %	10.3 %	6.6 %	4.2 %	3.3 %	5.2 %
<i>With additional medication</i> (n= 1515)						
very good and good	85.8 %	59.4 %	60.4 %	62.7 %	70.5 %	83.2 %
satisfactory	9.8 %	20.4 %	22.9 %	30.7940	23.5 %	11.7 %
unsuccessful or worsened	4.4 %	10.2940	16.7 %	6.7 %	5.9 %	5.1 %
<i>Without additional non-medical measures</i> (n= 2073)						
very good and good	86.1 %	70.3940	66.6 %	75.2 %	85.7 %	81.6 %
satisfactory	10.1 %	19.4 %	24.1 %	19.6 %	11.1 %	13.3 %
unsuccessful or worsened	3.8 %	10.3 %	9.2 %	5.2 %	3.2 %	5.1 %
<i>With additional non-medical measures</i> (n= 875)						
very good and good	87.4 %	86.3 %	65.7 %	81.3 %	78.6 %	86.3 %
satisfactory	8.1 %	4.5 %	20.0 %	18.8 %	14.3 %	8.8 %
unsuccessful or worsened	4.4 %	9.1 %	14.3 %	0.0 %	7.1 %	4.9 %
<i>Total therapeutic measures</i> (n= 3009)						
very good and good	86.5 %	71.0 %	66.1 %	75.2 %	84.5 %	82.7 %
satisfactory	9.5 %	18.5 %	23.6 %	19.9 %	11.7 %	12.2 %
unsuccessful or worsened	4.0 %	10.6 %	10.2 %	4.8 %	3.9 %	5.1 %

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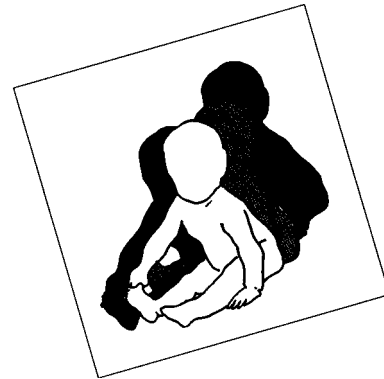
# Viburcol®

Homeopathic Medication



**Suppositories** ●  
**for infants and children.**

**In conditions of restlessness** ●  
**with or without fever.**



**Active ingredients:** 1 suppository contains: Chamomilla 1X, Belladonna 2X, Dulcamara 4X, Plantago major 3X 1.1 mg each; Pulsatilla 2X 2.2 mg; Calcarea carbonica 8X 4.4 mg.

**Package size:** Packs containing 12 rectal suppositories of 1.1 g each.

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