

# The Therapy of Vertigo with a Combination Homeopathic Preparation

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## Abstract:

*In an application monitoring study, the effectiveness and tolerance of a homeopathic combination preparation were investigated and documented for 3,386 patients suffering from vertigo originating from various causes. Breakdown of causes of the vertigo revealed a large share of patients with multicentric vertigo (39.8%). The following were among the most frequent single causes of vertigo among the patients studied: cardiovascular origins (25.6%), orthopedically associated causes (14.1%), luxury/junk foods and stimulants as provocation (4.7%), and metabolically associated genesis (3.8%). All the available forms of administration of the preparation were involved in this study: tablets, drops, and ampules. In 15.4% of the cases treated, a combination of these forms was applied. For 51.7% of the patients, Vertigoheel was administered in conjunction with adjuvant medication. On the basis of the entire test population of 3,386 patients, therapeutic success with the assessment very good, good, or satisfactory was achieved for 91.9% of the cases. The tolerance of the preparation was judged as very good.*

## 1. Introduction

The homeopathic medication Vertigoheel is available on the market in the

form of tablets, drops, and ampules. It is a homeopathic preparation produced and distributed by the company Heel Biotherapeutics, of Baden-Baden, Germany. The exclusive U.S. distributor of Heel Biotherapeutics is Biological Homeopathic Industries (BHI) Inc. in Albuquerque. The constituents of Vertigoheel are *Cocculus indicus* (Indian cockles), *Conium maculatum* (spotted hemlock), *Ambra grisea* (ambergris), and homeopathically attenuated petroleum. The area of application of this preparation is vertigo of various origins. This indication coincides with the homeopathic drug pictures of the constituent substances. *Cocculus* and *Conium* are indicated in cases of vertigo, nervous disorders, and nausea. Homeopathically attenuated petroleum is called for in cases of gastritis when associated with nausea and vertigo. Ambergris therapeutically acts in the sphere of the nervous system, in cases of central and autonomic disorders [7].

Data on therapeutic experience with the above named preparation have been documented in a great number of publications [1,2,6,8, and 9]. In experiments carried out under clinical conditions in the Research Institute for Neurotology in Bad Kissingen, Germany, investigations have furthermore been conducted to clarify the processes of therapeutic action of the marketed preparation, and the significance of its individual constituents [3, 4, and 5]. The objective of the drug application survey published in the following was to complement the previously con-

ducted research and to arrive at further insights into the effectiveness and the tolerance of this preparation under conditions of extensive therapeutic application.

## 2. Methods of investigation

### 2.1 Conduct of testing

A total of 487 physicians from different specialist areas took part in this drug application survey. The participating physicians used a standardized questionnaire to record therapeutic data on patients who suffered from vertigo originating from various causes, and who were treated with the above stated homeopathic preparation. This study did not contain any particular criteria for inclusion or exclusion of patients, since the investigation was intended to realistically cover a representative population of patients treated in actual medical practice with the homeopathic preparation. In addition to information on age and sex, the documentation included for each individual case a description of the vertigo symptom complex. This description was provided in accordance with the data-acquisition form published as the Neurotological Case-History Questionnaire (NODEC).

This questionnaire and the procedure were designed to offer sufficient differentiation and breakdown of general vertigo into the following symptoms:

- Sway (staggering vertigo).
- Elevator vertigo (a sensation of lifting).

- *Rotatory vertigo.*
- *Tendency to fall.*
- *Scotodinia*  
(dizziness with blurring of vision and headache).
- *Unsteady balance*  
(feeling of balance insecurity).

In the questionnaire used, it was possible to record more than one symptom for a single patient. Also recorded were the duration of symptoms in general, as well as the duration of the individual attack. The physicians were asked to assign the causes of the symptoms to a listing already given on the documentation form. It was also possible to add further information in the form of plain text. The participating physicians also recorded whether additional medication was taken at the same time as the homeopathic preparation under study; if so, the name of the preparation was entered.

The choice of the forms of administration and of the mode of application of the homeopathic preparation under study was left to the discretion of each physician. The general guideline for doses of tablets and drops, however, was recommended from the package insert: i.e., 3 tablets taken 3 times a day, and 15-20 drops taken 3 times a day. For the injection solution, the physicians were able to choose a dose from the following:

-1 ampule daily; -2 ampules per week; -1 ampule per week.

The physicians were requested to enter any deviation from the above recommendations in the section of the questionnaire for plain text. The term of therapy depended on the progress of the illness.

The participating physicians rated the results of therapy with one of the following classifications for each case:

- Very good
- Good
- Satisfactory
- Unsuccessful (i.e., without change)
- Caused worsening

Undesired side effects were entered

as plain text.

The physicians returned the filled-out questionnaires over a period of one and one-half years: from January of 1988 until July of 1989. Over this period, the physicians participating in the drug application survey returned 3,402 completed questionnaires.

## 2.2 Preparation of data and statistical analysis

From all the questionnaires returned, 16 (0.47%) were incomplete: i.e., they failed to indicate the type of symptom complex encountered, or they lacked classification grading of therapy results. These forms were checked for possible entry of any undesired side effects (there were none), and were then discarded as not useful for further analysis. As a result, 3,386 questionnaires were able to be used for final statistical evaluation.

The data were analyzed by methods of descriptive statistics. Representation of the characteristics entered took place in part through use of basic statistical values (mean value and standard deviation), and in part through their absolute or percentage frequency distribution. Since the participating physicians did not answer all questions on all questionnaires, the totals of percentage values given in the reports do not always amount to 100%.

## 3. Results of the survey

### 3.1 Description of the patient population

Among the 3,386 patients included in data analysis, women (65.1 %) were represented more frequently than men (34.4%). The average age was 62.17 (s = ± 16.98 years). Fig. 1 provides a distribution of the age and sex data.

The most frequently observed form of vertigo was sway (staggering vertigo): 52.7% of the patients. The second most frequent symptom reported was unsteady balance: 49.4% of the cases. The remaining symptoms followed, in decreasing order of frequency: rotatory vertigo (40.5 %), tendency to fall (27.0%), and scotodinia (26.9%). The least frequent complaint - only 6.8% of the cases - was elevator vertigo (a sen-

sation of lifting). These figures also include multiple symptoms for individual patients. In 62.9% of all patient questionnaires, the physician checked off more than one of the above-stated symptoms to describe the vertigo symptom complex of a single case. Three or more symptoms were entered on 29.3% of the forms.

The majority of patients had already suffered from their symptoms for several months or longer (52.0%) before they consulted a physician for vertigo symptoms and were registered in the survey. Before the survey, symptoms had lasted for weeks for 22.8%, for days for 19.8%, for a number of hours for 4.3%. When questioned on the duration of their vertigo attacks, 19.5% of the patients indicated 1-2 seconds, and 45.9% reported a number of minutes. Attacks lasting for hours were suffered by 17.2%, and 5.8% of the cases involved even longer duration of the episodes: for days, weeks, or even months. Permanent vertigo was recorded for 10.8% of the patients.

In analysis of the results, patient data were broken down into groups according to the various different factors associated with the vertigo: causative elements as well as fundamental illnesses. In assigning the cases to the individual groups (I-IV), however, only those patients were included for whom one single causative factor was recorded as responsible for the vertigo. All patients with more than one causative factor entered on their forms were grouped into the additional classification "Combination of factors."

The following overview indicates the breakdown of patients into the individual causative groups:

- Group I: Luxury or junk foods and stimulants as cause of vertigo (e.g., caffeine, nicotine, etc.): 159 patients (4.7%)
- Group II: Vertigo associated with cardiovascular factors: 868 patients (25.6%)
- Group III: Vertigo associated with metabolic factors (e.g., as a result of Diabetes mellitus): 128 patients (3.8%)
- Group IV: Vertigo associated with

orthopedic factors (e.g., degenerative alterations of the cervical spine): 478 patients (14.1%)

- Group V: Combinations of more than one cause: 1348 patients (39.8%)

These five groups included all causes of vertigo which were documented for more than 100 cases treated. The remaining patients were distributed among a greater number of additional causative factors such as the following:

- Traumata: 93 cases
- Cerebral degeneration: 59 cases
- Pharmaceuticals: 34 cases
- Psychogenic factors: 25 cases
- Infectious illnesses: 12 cases.

The remaining miscellaneous causes each included only a few cases.

Table 1 depicts the most essential patient data relating to the entire population and to the five main groups of causes. It is noteworthy here that the average age of the patients in Group I (vertigo associated by luxury/junk foods and stimulants) is definitely lower than that of the patients in the overall population and in the other groups of causative factors. The distribution according to sex does not in Groups II-V deviate significantly from that of the entire population (34.4% men and 65.1% women). In Group I, however, the distribution has clearly shifted toward the masculine side: 51.6% men and 46.5% women. It is also clearly evident that the patients from this group had suffered from vertigo for only a relatively short time before consulting a physician. Whereas the most frequent duration of complaints was several weeks to months for the other types of vertigo, more than one-third of patients with vertigo related to junk/luxury foods and stimulants had suffered only for a few days.

### 3.2 Medication

Analysis of data on the forms of administration of the homeopathic combination preparation under study here reveals that physicians prescribed tablets for 50.2% of the patients, drops for 44.9%, and ampules for 20.8% (these data include all cases, including pre-

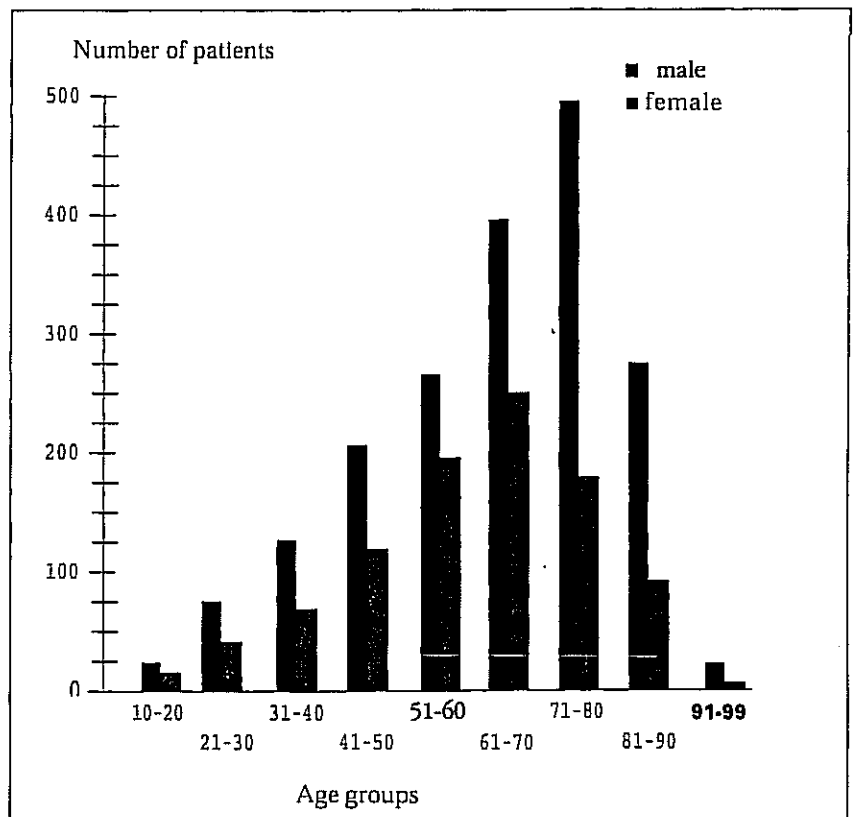


Fig. 1: Age and sex distribution of the patients.

	Group I	Group II	Group III	Group IV	Group V	Total patient population
	n = 159	n = 868	n = 128	n = 478	n = 1,348	n = 3,386
Factors associated with vertigo	Luxury foods / stimulants	Cardio-vascular factors	Meta-bolic factors	Ortho-pedic factors	Combi-nation of factors	
Average age in years	47.16	65.79	56.96	57.87	66.36	62.17
(Sex in %)	m: 51.60 f: 46.50	m: 34.10 f: 65.70	m: 33.60 f: 66.40	m: 32.40 f: 66.70	m: 32.10 f: 67.50	m: 34.40 f: 65.10
Duration of complaints (in %)						
for hours	17.60	2.90	0.80	4.80	2.90	4.30
for days	34.60	17.60	18.00	26.10	14.90	19.80
for weeks	25.10	23.80	37.50	22.60	21.60	22.80
for months	11.90	29.30	27.30	28.20	30.10	27.50
for years	8.80	23.30	14.80	16.90	27.70	23.00
for decades	0.00	1.20	0.80	1.00	2.10	1.50

Table 1: Elaboration on the patients admitted to the post-marketing survey

scription of more than one form for a single patient). Considering the sub-population consisting of those patients for whom only one form of administration was prescribed, tablets again led the list, with 40.9%, and were followed by drops with 35.4% and ampules with 8.3%. A total of 15.4% of the patients received a combination of more than one form of the medication. Fig. 2 shows the frequency of the individual combinations. This illustration reveals that the prescribing physicians relatively often combined the ampule form of the preparation with one of the two oral forms - whereas the combination of drops and tablets was less frequent.

The ampule solution of the preparation was injected IM in 49.2% of the cases, and IV in 31.5%. Subcutaneous application took place for 12.5%, and intracutaneous, for 0.8%. In 7.4% of all cases, a further form of application was used: orally administered ampules. In such cases, the patient as a rule empties the contents of an ampule into a glass of water and sips it throughout the course of a day. Since a small number of the patients also combined different possibilities of ampule administration, the sum of percent figures here is also slightly more than 100%.

With regard to doses prescribed for the tablet form of administration, 81.1% of the cases treated received the dose recommended on the questionnaire: 3 tablets, 3 times a day. In 6.3% of the cases, the dose was 1 tablet, 3 times a day, and in 4.0%, 2 tablets, 3 times a day. Adherence to the recommended dose was even higher for the preparation as drops: 93.7% of the cases received the suggested amount from the prescribing physicians: 15-20 drops, 3 times a day. The ampule dose for 36.2% of patients was 1 ampule daily; for 31.5%, it was 2 ampules per week. The total remaining levels of dosage - insofar as they were precisely indicated on the reporting forms-amounted together to only 6.5% of the cases.

### 3.3 Duration of medicamentous therapy

On the basis of the entire patient

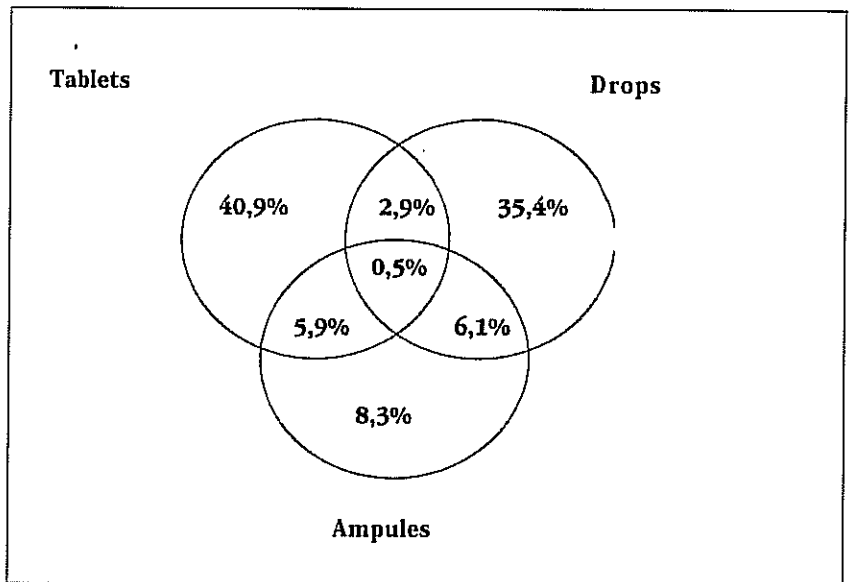


Fig. 2: Percent breakdown of actual employment of the various forms of administration of the homeopathic combination preparation.

Main classification in the German Physician's Desk Reference	Classifications of medication reported more than 50 times among the total population (multiple reporting possible)
Cardioactive agents	721
Agents promoting blood circulation	364
Beta-blockers and calcium antagonists	231
Antihypertensives	196
Analgesics / antirheumatics	196
Antidiabetics	186
psychopharmacological drugs	173
Coronary therapeutic agents	166
Series of preparations / homeopathic agents	162
Diuretics	143
Antihypotensives	77
Gastrointestinal medication	62
Antiemetics / Vertigo medication	56
Lipid reducers	52

Table 2: Breakdown of the adjuvant medication employed among the total population, according to main classifications in the German Physician's Desk Reference.

population, the duration of therapy with the homeopathic preparation under study was as follows: 9.6% of cases less than one week, 42.6% between one week and one month, and 46.2% longer than one month. The vertigo patients in Group I (luxury/junk foods and stimulants) received the preparation, on the average, for a term definitely shorter than that of patients in the other causal factor groups. In only 19.5% of Group I cases did therapy with the preparation under study last longer than one month. In each of the remaining patient groups, the length of therapy did not significantly deviate from the mean length of therapy for the entire patient population.

Upon analysis of the duration of therapy in relation to the length of time which the patients suffered from their symptoms before consulting a doctor, the following becomes apparent: as a rule, the longer the term of therapy with the homeopathic combination preparation, the longer the previous duration of the vertigo symptom complex before seeking medical aid. Of all the patients who complained of vertigo symptoms which had lasted only a few hours before onset of therapy, almost two-thirds (62.3%) required homeopathic therapy for a period lasting less than one week. If the symptoms had already lasted for days, therapy of up to a week was sufficient in only 24.6% of the cases. For 13.0% of these patients, furthermore, therapy with the preparation was necessary for even longer than one month. With increasingly longer previous duration of complaints, the share of patients correspondingly increased who needed therapy for more than one month. For example: in the group which experienced vertigo for several weeks, the percent of treated cases with a therapy duration of longer than one month was 33.6%; for the group with a case history of vertigo for several months, this figure was 59.9%. If the vertigo symptoms had already lasted for several years or longer, treatment with the homeopathic preparation required more than one month in 76.3% of cases.

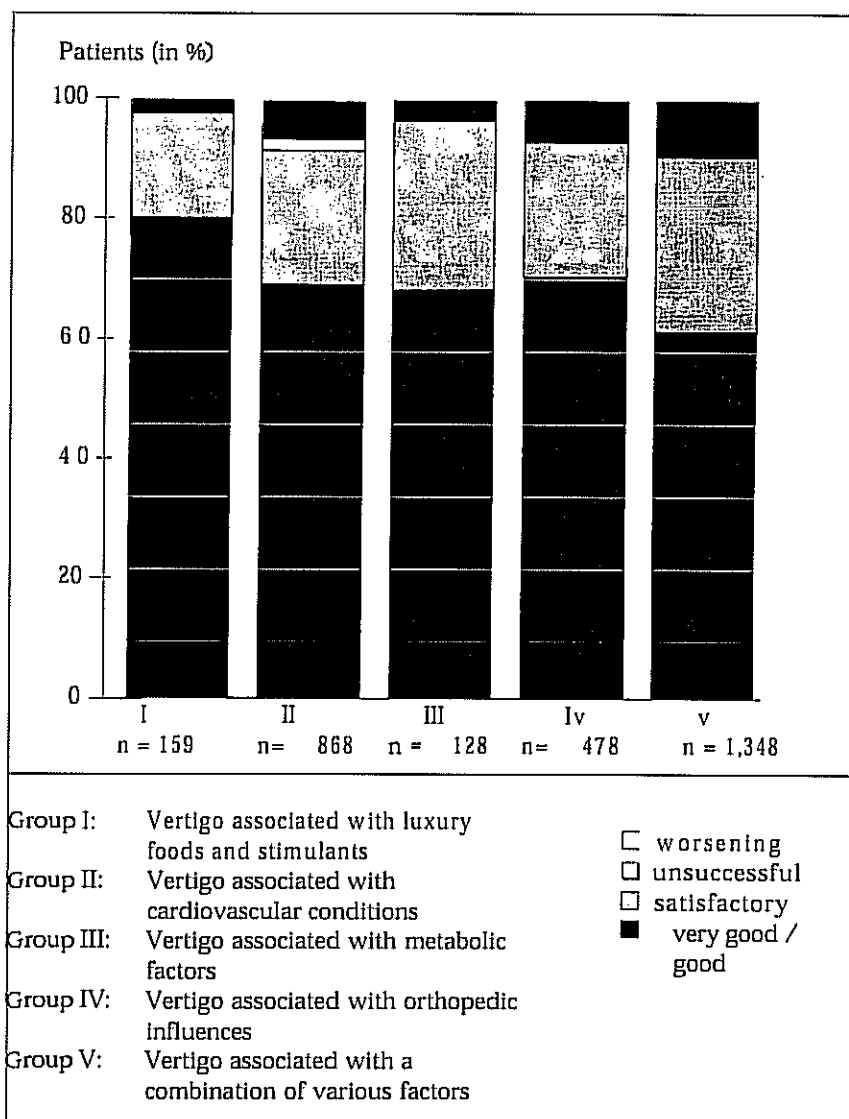


Fig. 3. Therapy results achieved with the homeopathic combination preparation being studied, when administered among patients with vertigo associated with the above-listed factors (n = 2,981).

### 3.4 Adjunctive medication

During therapy with the homeopathic preparation under study, 51.7% of the patients received additional medication; some of the patients took several other remedies. The breakdown of simultaneously prescribed adjunctive therapy in accordance with the main classifications of the German Physician's Desk Reference reveals that cardioactive agents were the most frequently prescribed, followed by agents promoting blood circulation, and by

beta-blockers and calcium antagonists (see Table 2). Adjunctive preparations from the group of antiemetics / vertigo medication (not including the homeopathic preparation under study) were simultaneously prescribed only in 56 cases (1.6%). These data reveal that, in the great majority of all cases, the adjunctive medications entered on the questionnaires were prescribed for the therapy of accompanying disorders, and not for direct treatment of the vertigo symptom complex itself.

	Results of therapy (in %)		
	Very good / good results	Satisfactory results	Unsuccessful
<b>Diagnosis</b>			
Staggering vertigo (sway) (n = 1,784)	67.7	24.6	7.7
Elevator vertigo (n= 230)	73.4	19.6	7.0
Rotatory vertigo (n= 1,373)	67.1	25.1	7.8
Tendency to fall (n= 913)	60.7	27.8	11.5
Scotodinia (dizziness with blurring of vision and headache) (n = 911)	69.9	22.6	7.5
Unsteady balance (n = 1,673)	66.5	24.9	8.6
<b>Forms of administration</b>			
Ampules (exclusively) (n = 281)	71.1	21.4	7.5
Drops (exclusively) (n= 1,198)	68.3	24.5	7.2
Tablets (exclusively) (n = 1,385)	64.0	25.8	10.2
<b>Mode of administration</b>			
Intramuscular (exclusively) (n= 137)	75.2	16.8	8.0
Intravenous (exclusively) (n= 85)	80.0	17.6	2.4
Subcutaneous (exclusively) (n= 29)	51.7	44.8	3.5
Oral (exclusively) (n = 2,741)	66.0	25.2	8.8

Table 3 Results of therapy, broken down by the type of vertigo symptom complex, as well as by the forms of administration and type of application of the homeopathic combination preparation under study

This fact is of special significance in assessment of the later presented therapy results with the homeopathic preparation under study. At the same time, however, it must be taken into account that successful therapy of the fundamental disorder - e.g., digitalis glycosides for cardiac insufficiency, or insulin or oral antidiabetics for Diabetes mellitus - will indeed also contribute

to relief in the vertigo symptom complex.

In Group I (vertigo associated with luxury/junk foods and stimulants), the share of patients receiving adjunctive medication was smallest: only 8.8%. In contrast, the second-highest percentage share of patients with adjunctive therapy (52.2%) came from the group

of patients who were treated with the homeopathic combination preparation for vertigo of cardiovascular origins. These patients primarily received simultaneous therapy with cardioactive agents, agents promoting blood circulation, and anti-hypertensives. In Group III (vertigo associated with metabolic factors), 39.8% of the patients received adjunctive medication: most frequently, they were prescribed antidiabetics. The group of patients with the highest rate of cases receiving adjunctive medication was Group V: vertigo with combinations of more than one cause. In this group, 67.9% obtained adjunctive remedies. This is hardly surprising, since cases characterized by polypathia are of course generally treated by multimedicamentous therapy.

### 3.5 Results of therapy

On the basis of the entire patient population, therapy results were assessed as "very good" or "good" in 67.5% of the cases treated. In addition, satisfactory therapeutic success was judged for 24.4% of the cases. As a result, a total of 91,970 of the patients was successfully treated under the homeopathic preparation under study. Only 7.9% of the cases experienced no improvement in their condition. In 0.2%, a worsening of the symptom complex was determined during the period of observation.

Patient Group I - the group with luxury or junk foods and stimulants as cause of vertigo - experienced the highest rate of very good and good results: 80.5%. In the remaining Groups II-V, between 63.6% and 70.1% of the patients completed their therapy with "good results or better. Fig. 3 presents the therapy results for all of the five major causally classified groups. Table 3 also breaks down the results of therapy according to the type of vertigo symptom complex, as well as the forms of administration and type of application of the homeopathic combination preparation under study. These data reveal that the preparation being investigated can especially achieve excellent therapeutic effects in

treatment of elevator vertigo.

For patients who received vertigo therapy exclusively from ampules, "very good" or "good" results were obtained in 71.1% of the cases. In therapy only with drops, this share was 68.3%, and exclusive treatment with tablets enabled a quota of 64.0%. Intravenous injection enabled 80.0% "very good" or "good" results, which was the best therapeutic success achieved from all forms of application. At the same time, "good" therapy success or better followed for 66.0% of patients from purely oral administration - a figure which included all the oral forms: tablets, drops, and orally administered ampule contents.

Under monotherapy, with employment of only the homeopathic preparation under study, 76.1 % of the cases enjoyed "very good" or "good" results, whereas equivalently good success was available for only 60.5% of those who received the homeopathic remedy along with other medication at the same time. Tables 4 and 5 present detailed data on therapy results with and without adjunctive medication.

### 3.6 Tolerance of the preparation

The tolerance of the preparation investigated can be assessed as very good. The question as to the appearance of side effects was answered by "yes" on only 9 of a total of 3402 questionnaires. From the explanatory remarks given in two of these cases of alleged side effects, however, it can be assumed with almost complete certainty that no actual side effects can be attributed to the homeopathic preparation under study. In one of these cases, the patient refused to take the preparation, on the alleged grounds that it would taste bad. In one other case, the only elaboration given was the note "Isoptin," which leads to the assumption that the indication of side effects refers to the adjunctive medication. Primary therapeutic response - an unpleasant primary reaction - was observed among two patients: a phenomenon well known in conjunction with homeopathic remedies. This reaction is very brief in most cases and

	Group I	Group II	Group III	Group IV	Group v	Total patient population
	n = 144	n = 396	n = 70	n = 297	n = 371	n = 1,520
Factors associated with vertigo	Luxury foods / stimulants	Cardio-vascular factors	Meta-bolic factors	Ortho-pedic factors	Combi-nation of factors	
Results of therapy (in %)						
Very good / good success	82.0	78.2	74.3	74.8	74.7	76.1
Satisfactory results	16.0	18.2	22.9	18.5	17.8	18.8
Unsuccessful results	2.1	3.5	2.9	6.7	7.5	5.1

Table 4: Therapy results for those patients who received the preparation under study as monotherapy

	Group I	Group II	Group III	Group IV	Group v	Total patient population
	n = 14	n = 456	n = 51	n = 160	n = 915	n = 1,752
Factors associated with vertigo	Luxury foods / stimulants	Cardio-vascular factors	Meta-bolic factors	Ortho-pedic factors	Combi-nation of factors	
Results of therapy (in %)						
Very good / good success	64.3	62.1	60.8	59.4	59.9	60.5
Satisfactory results	28.6	28.5	35.3	30.6	29.1	28.9
Unsuccessful results	7.1	9.45	3.9	10.0	11.0	10.6

Table 5: Results of therapy for those patients who received the investigated preparation together with adjunctive medication

is considered by homeopathic therapists to be a welcome sign of positive response to the preparation. Both of these patients in fact soon experienced definite relief from their vertigo symptom complexes in the further progress of therapy.

In two additional cases, the patients reported slight nausea after adminis-

tration of the homeopathic combination preparation. There was also one case of each of the following side effects: fatigue, headache, and nausea and vomiting. These few cases of undesired side effects concern only minor disorders in the form of general subjective sensations of ill health. A causal interrelationship between administration of the preparation and the

observed phenomena has, moreover, not been confirmed.

#### 4. Interpretation of Results

Post-marketing surveillance in the form of drug application surveys represents an effective method of verifying the tolerance of a medicinal product on the market. These methods also provide valuable data on the patients treated, the mode of application of the preparations, and therapy results achieved under realistic therapeutic conditions.

The drug application survey presented here demonstrates that multi-causal processes were frequently responsible for the complex of vertigo symptoms observed among the patients who were treated by physicians with the homeopathic combination preparation under study. In 39.8% of the cases, more than one cause for the vertigo complaints was entered on the questionnaire. Among those patients for whom a definite assignment of causes was possible, cardiovascular disorders (25.6% of the cases) and orthopedic causes (14.1 %) played the most prominent roles. In addition, however, vertigo after abuse of junk/luxury foods and stimulants (4.7% of the patients covered) and vertigo associated with metabolic disorders such as Diabetes mellitus and the like (3.8% of the cases) were also frequently treated with the homeopathic combination preparation.

The rate of therapeutic success was by far the best for the patient group with vertigo associated with junk/luxury foods and stimulants: 80.5% of this group obtained "very good" and "good" results. In interpretation of these results, however, it may be assumed that a significant number of patients in this group behaved more sensibly with junk/luxury foods and stimulants during the period of therapy, which would thereby contribute to the good therapeutic success. In the remaining causally associated groups, the share of "good" or better therapeutic

results lay between 63.6% and 70.1 %. The share of unsuccessful results in the least favorable group of patients (Group V, with various different factors contributing to vertigo) was 10.0%.

The homeopathic preparation under study was administered together with adjunctive medication for 51.7% of the patients. The share of "very good" or "good" therapeutic results was lower for this subset of patients than for the treated cases for whom the homeopathic preparation under study was administered alone. These data do not, however, justify the conclusion that adjunctive medication impaired the effectiveness of the homeopathic preparation. The very fact that additional medication was prescribed demonstrates that the cases involved were correspondingly more severe, and that from the very beginning a lower success rate was consequently to be expected.

The excellent reputation of this homeopathic combination preparation for good tolerance - well known as it has been for decades now - was verified by the results of this study. Out of 3,400 cases treated here, only seven patients reported undesired side effects. Without exception, they were minor and only temporary in nature. This extremely low rate of side effects is especially significant in the risk-benefit considerations undertaken in decisions to employ the homeopathic preparation under study. As a result of its reliable effectiveness and outstanding tolerance, this preparation satisfies all requirements placed on a modern medication for therapy of vertigo. The drug application survey described in the above has assembled valuable information on the possibilities of administration of the preparation being studied, and has confirmed insights which had previously been gained.

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