Cerebral Function Disorders and Biological Therapy

An Application Study with 731 Patients

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Summary

Cerebrum compositum is a homeopathic combination medication utilized as base therapy in treating a great number of various disturbances in cerebral function. The goal of the prospective, multicentric application study at hand was to document therapeutic usage of Cerebrum compositum on an extensive patient collective. The factors of dosage, application intervals, therapeutic duration, and adjuvant therapy were individually determined by the attending physician in each separate case. Upon concluding data compilation, 731 documented therapeutic cases were available for statistical evaluation. This application study substantiates Cerebrum compositum as therapeutically successful within the manufacturer-specified indicational fields. The attending physicians assessed therapeutic results as either "very good" or "good" in 70.5 % of the cases, based on the entire patient collective. The preparation was well tolerated.

1. Introduction

The brain is one of the most complex organs within the human body. The cerebral cortex alone comprises approximately 15 billion neurons, multifariously conjoined with one another through their dendrites and axons. Roughly 800 ml of blood flows through the human brain each minute (6). Circa 15 % of the cardiac output (l/min) is utilized within the brain, although its approximate weight constitutes a mere 2 % of bodily poundage (5). These figures illustrate the extremely high degree to which cerebral tissue is metabolically engaged.

Affections or functional deficiencies within an organ of such complexity generally require therapeutic strategy which takes action on various levels simultaneously. Based upon the concepts of homotoxicology according to Dr. H.-H. Reckeweg, Cerebrum compositum (manufactured by Biologische Heilmittel Heel GmbH of Baden-Baden, Germany) provides a medicinal agent which unifies an abundance of differing active factors. Due to its broad therapeutic spectrum, this preparation is well suited to serve as fundamental therapy in treating a wide variety of disturbances in cerebral function.

Exclusively composed of homeopathic constituents, Cerebrum compositum is produced in accordance with the directives stipulated within the German Homeopathic Pharmacopoeia (HAB). The preparation's broad spectrum of efficacy is the result of its combined variety of botanical and mineral components. Cerebrum compositum additionally contains homeopathically potentized organ-extracts (Cerebrum suis, Embryo suis, Hepar suis, and Placenta suis) which specifically stimulate organic function, as well as the nosodes Luesinum and Medorrhinum, two constitutional remedies for exerting a positive influence on the organism's general responsive status. The overall action of Cerebrum compositum is directed not only toward improving brain function (including memory), but also toward alleviation and prevention of arteriosclerotic circulatory disturbances with consequential deterioration in cerebral performance, a factor particularly valuable in the treatment of elderly patients. This preparation may also be successfully employed in pediatric therapy in cases of disturbed emotional development, scholastic difficulties, or general weakness in mental performance.

A number of sources in relevant literature emphasize the manifold applicational possibilities offered by Cerebrum compositum. E. Zoubek (8) recommends the preparation for use in post-apoplectic therapy. In his publication "Therapy in the Presence of Geriatric Heart" (3), J. John indicates therapeutic possibilities for treating cases of arteriosclerotic and other circulatory disturbances of the brain. W. Frase (1) utilizes Cerebrum compositum for migraine patients within the framework of progressive auto-sanguis therapy. F.-A. Graf von Ingelheim (2) refers to Cerebrum compositum as a preparation specially for comprehensive improvement of cerebral function. K. Küstermann (4) employs Cerebrum compositum in treating arteriosclerosis, including occasional usage in the form of a combination injection, administered within a blend of further antihomotoxic preparations. W. Wachter (7) utilizes the preparation in treating arteriosclerotic disturbances of the brain.

While each of the above-mentioned authors illuminated merely a partial aspect of Cerebrum compositum's applicative range, the following application study (encompassing 731 therapeutic cases) was designed to investigate this

preparation's entire indicational spectrum in regard to administration, efficacy, as well as tolerance.

2. Procedure

The application study (hereafter abbreviated "a.s.") was conducted in Germany and Austria from April through September of 1993. 77 physicians in private practice, predominantly general practitioners, participated in this investigation. Documentation of therapeutically-relevant data was procured by means of standardized questionnaires. Neither inclusion nor exclusion criteria of any kind were designated in regard to selection of cases for documentation, as the study at hand was intended to comprehensively depict the various applicative possibilities of Cerebrum compositum within the medical practice. Upon concluding treatment, therapeutic results were assessed by means of a four-level rating scale ("very good" = patient completely free of complaints, "good" = marked improvement, "satisfactory" = slight improvement, and "unsuccessful" = condition unaltered or aggravated). Any undesired responses observed in connection with the application of Cerebrum compositum were to be described in detail on a separate form provided for this purpose.

Upon concluding data compilation, a total of 731 completed therapeutic cases were available for statistical analysis. The information entered on the questionnaires was recorded with the aid of a computer program and subsequently processed through descriptive evaluation.

3. Findings

Patient Collective

Forming 55% of the total collective, female patients were more highly represented within this a.s. than their male counterparts. Two-thirds of the participating patients were between 41 and 80 years of age, a distribution reflecting the fact that cerebral disorders generally occur more frequently during the latter half of life (Fig. 1).

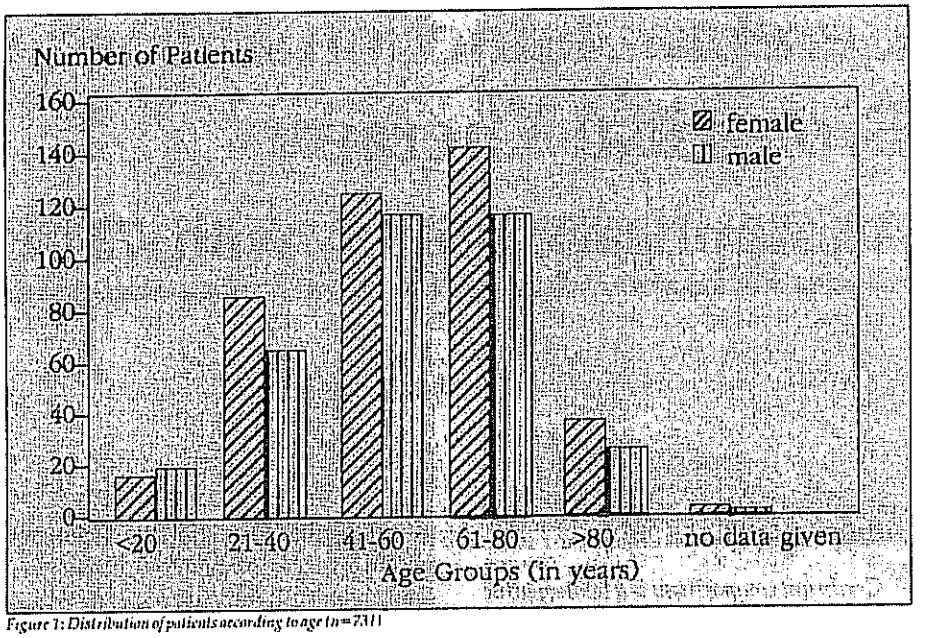

Figure 1: Distribution of patients according to age (n = 731)

Diagnostic Collective	Number of Patients
Irretentiveness	247 (33.8%)
Nervous exhaustion	237 (32.4%)
Arteriosclerosis	198 (27.1%)
Depression	197 (26.9%)
Neurodystonia	177 (24.2%)
Neuralgia	125 (17.1%)
State of agitation	72 (9.8%)
Condition ensuing concussion of the brain	61 (8.3%)
Parkinson's disease	39 (5.3%)
Multiple sclerosis	31 (4.2%)
Post-encephalitic condition	14 (1.9%)
Amyotrophic lateral sclerosis	8 (1.1%)
Miscellaneous diagnoses	99 (13.5%)

Table 1: Type and quantity of diagnoses determined (n = 731)

Diagnoses / Duration of Illness

For the purpose of facilitating assignment of individual patients to specific diagnostic groups, twelve diagnoses - each empirically known to represent a field of application typical for Cerebrum compositum - were pre-indicated on the data-procurement forms. The vast majority of patients was assigned to one of these proposed diagnostic collectives. Predictably, multiple diagnoses were designated in a number of cases, i.e. numerous patients received more than a single diagnosis. The most common diagnoses were irretentiveness, nervous exhaustion, arteriosclerosis, depression, and neurodystonia (Tab. 1). Such disorders as apoplexy, vertigo, tinnitus, etc., which were inappropriate for delegation to any of the twelve diagnostic groups indicated, were consolidated under the heading "Miscellaneous".

The following observations are made regarding the patient-collective as a whole: every fourth patient had been ill for a period of less than one month at commencement of the a.s., thus representation of acute affections was expectedly low. In every third patient, duration of illness was indicated as having persisted from 1 to 6 months. Approximately 16 % of the patients had suffered from the affection from 7 to 12 months, while the period of illness ex-

Principal Groups	Number of Patients
Circulation-promoting drugs	119 (32.7%)
Psychopharmacological agents	83 (22.8%)
Vitamin preparations	43 (11.8%)
Sedatives	20 (5.5%)
Homeopathic preparations	17 (4.7%)
Analgesic agents	15 (4.1%)
Depressants and stimulants	13 (3.6%)
Remedies for Parkinson's disease	12 (3.3%)
Antidepressants	8 (2.2%)

Table 2: Medicinal agents applied in prior treatment to over two percent of patients (n=364)

ceeded one year in 30 % of the patients. This relatively high proportion of patients suffering from prolonged illnesses suggests the majority of cases documented here were apparently "problem cases" which had failed to sufficiently respond to previous therapeutic measures.

Prior Medicinal Treatment

Nearly one-half of the patients included in this a.s. had received medicinal therapy for their affections at a previous time. The proportion of cases with prior medicamentous treatment varies among the individual diagnostic groups, at times to a considerable degree. The percentile rate of such cases is particularly high in the diagnostic collectives of multiple sclerosis (80.6 %), Parkinson's disease (79.5 %), and arteriosclerosis (71.7 %). The preparations applied prior to commencing Cerebrum-compositum therapy were classified into various principal groups in accordance with the P.D.R. Table 2 illustrates all such preparations applied in previous treatment to over two percent of the patients.

Dosage and Modes of Application

Recommended dosage of Cerebrum compositum is indicated in the Instructions for Use as injection of 1 ampule, 1 - 3 X weekly. As the findings of this a.s. illustrate, the physicians' preferred-dosage patterns reflect approx. 97 % to lie within this manufacturer-advised range (3 ampules weekly in 39.3 % ; 2 ampules weekly in 39.9 %; and 1 ampule per week in 17.4 % of all cases). In roughly 93 % of the patients, the dosage administered at the onset of treatment was maintained throughout the entire therapeutic period. Dosage was reduced in 7 % of the patients. In not a single case was the initially-selected dosage increased.

In accordance with the Instructions for Use, Cerebrum compositum may be applied through intramuscular, subcutaneous, intracutaneous, as well as intravenous injection. As the findings of this a.s. demonstrate, all of these applicative modes were employed in actual practice, although with varying frequency. Thus intramuscular administration was utilized in every second patient, and the subcutaneous technique in every fifth. Oral application of the ampule's contents (through swallowing) was employed in approx. 7 % of the patients. A combination of differing applicative modes was administered in a number of cases. Relative usage-frequency of the various modes of application is illustrated in Figure 2.

Adjuvant Therapies

During the course of this a.s., participating physicians were fundamentally permitted to administer both supplementary medication and non-medicinal therapeutic measures to their patients parallel to applying Cerebrum compositum. A total of 52 % of all patients received medicinal and/or non-medicinal adjuvant therapy. The remaining patients were treated by means of Cerebrum compositum as monotherapy. The preparations prescribed as medicinal supplementary therapy were classified into various principal groups in accordance with the P.D.R. (Tab. 3).

Comparison of the prescribed adjuvant medication with that employed in previous therapy reveals homeopathically-oriented preparations play a much more dominant role here, while application of allopathic preparations (such as circulation-promoting drugs and psychopharmaceuticals, for example) dropped markedly. The non-medicinal adjunctive measures essentially comprised dietary modification, ozone therapy, physiotherapy, and psychotherapeutic procedures.

Duration of Therapy

Overall observation indicates roughly one in every two patients was treated from two to five weeks, whereas therapy of briefer duration

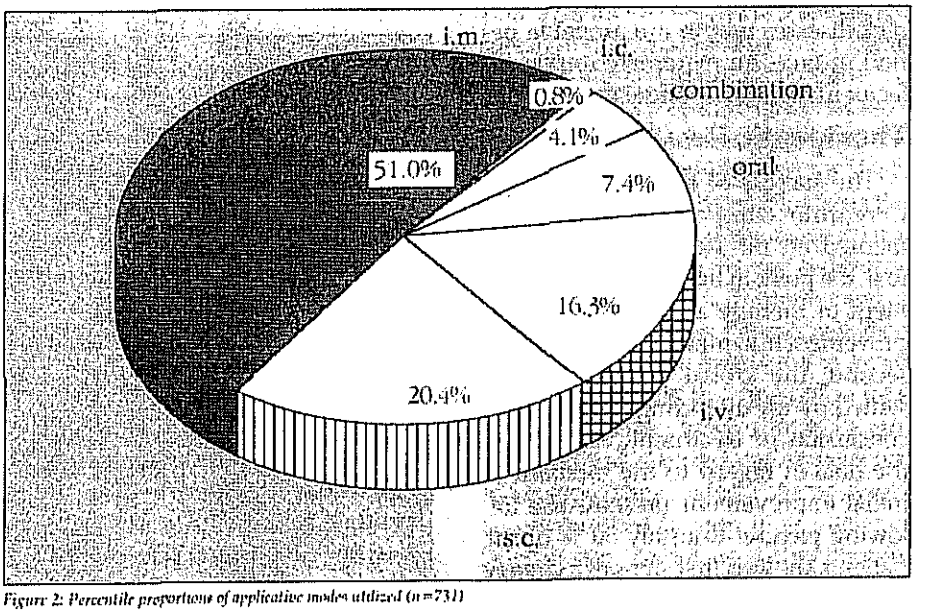

Figure 2: Percentile proportions of applicative modes utilized (n=731)

Principal Groups	Number of Patients
Homeopathic preparations	117 (39.0%)
Circulation-promoting drugs	76 (25.3%)
Psychopharmacological agents	36 (12.0%)
Vitamin preparations	26 (8.7%)
Sedatives	19 (6.3%)
Remedies for Parkinson's disease	18 (6.0%)
Cardiac remedies	8 (2.7%)

Table 3 Medicinal agents employed as adjuvant therapy in over two percent of the patients (n = 300)

was documented in only 10 % of the patients. Reflecting the large number of cases of a chronic nature, approximately 40 % of the entire collective was treated with Cerebrum compositum for a period exceeding six weeks. Individual study of therapeutic duration for each of the various diagnoses reveals, for example, the group registering the highest quantity (67 %) of patients treated less than 3 weeks to be those having suffered concussion of the brain. Syndromes such as amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, and post-encephalitic conditions, on the other hand, ordinarily required treatment over a period of six weeks and more. Generalization of the periods indicated here must be avoided, however, as therapeutic duration is directly dependent upon such individual factors as the degree of pathological severity, age of the patient, and any accompanying illnesses. This data substantiates the capability of homeopathic medication to treat even complex diseases within a reasonable period of time, an extremely important factor in regard to patient compliance.

Therapeutic Results

The success of treatment utilizing Cerebrum compositum was documented on the basis of two criteria: first, the point in time after commencement of therapy at which initial improvement in symptoms occurred; and second, the global evaluation presented by the attending physician on conclusion of treatment. Analysis of the data in regard to the moment of initial improvement presents the following picture: Roughly 30 % of the patients showed first signs of a change for the better within the initial week of treatment, while these became evident in every second patient within a therapeutic period of two to five weeks. In merely 6.0 % of the cases was therapeutic duration of six to eight weeks necessary prior to appearance of the first signs of improvement. Approximately 3 % of the total collective responded with betterment only subsequent to receiving more than eight weeks of therapy. 8.5 % of the cases reported no improvement in the intensity of complaints.

On reviewing the results of global therapeutic evaluation for the entire patient collective, one observes that therapeutic response was rated as "very good" for every fifth patient (21.1 %), and as "good" for each one in two (49.4 %). "Satisfactory" therapeutic results in the form of slight improvement related to discomfort or symptoms were achieved in an additional 20.9 % of the patients. In merely 8.5 % of the cases was therapy employing Cerebrum compositum evaluated as unsuccessful. In one of these cases, side-effect-linked aggravation of the patient's condition was observed.

With the objective of gaining further information as to which complaint-constellations and/or symptom-pictures responded particularly well to therapy utilizing Cerebrum compositum, individual assessment of the therapeutic results achieved in each diagnostic collective was carried out as well. The differences among the various diagnostic groups thereby became apparent, which were quite marked in certain instances. The percentage of very good to good therapeutic results ranged between 90 % and 25 %, depending upon the illness in question. Part of the grounds for this disagreement may lie within the affections themselves. Thus, for example, no adequate therapy exists to this day (i.e. none which promises permanent success) for multiple sclerosis; Parkinson's disease, too, has remained incurable to date. The therapeutic results shown within these diagnostic groups, therefore, are strictly to be viewed as relative (Tab. 4).

In order to estimate the degree of influence which adjuvant treatment exerts upon therapeutic results, the patients having received Cerebrum compositum as the sole therapeutic measure were analyzed, focusing particularly on the results this therapy had attained. The in-

Diagnostic Collective	Very good/ good	Satis-factory	Un-successful
Condition ensuing concussion of the brain (n = 61)	90.2	8.2	1.6
Nervous exhaustion (n = 237)	77.6	17.7	4.7
Neurodystonia (n = 177)	77.4	18.1	4.5
Neuralgia (n = 125)	76.8	18.4	4.8
State of agitation (n = 72)	72.2	18.1	9.7
Depression (n = 197)	67.5	23.9	8.6
Irretentiveness (n = 247)	63.9	26.3	9.3
Arteriosclerosis (n = 198)	58.6	28.8	12.1
Post-encephalitic condition (n = 14)	57.1	28.6	14.3
Parkinson's disease (n = 39)	46.2	43.6	10.2
Multiple sclerosis (n = 31)	38.7	48.4	12.9
Amyotrophic lateral sclerosis (n = 8)	25.0	50.0	25.0

Table 4. Therapeutic results within individual diagnostic collectives (indicated in percent)

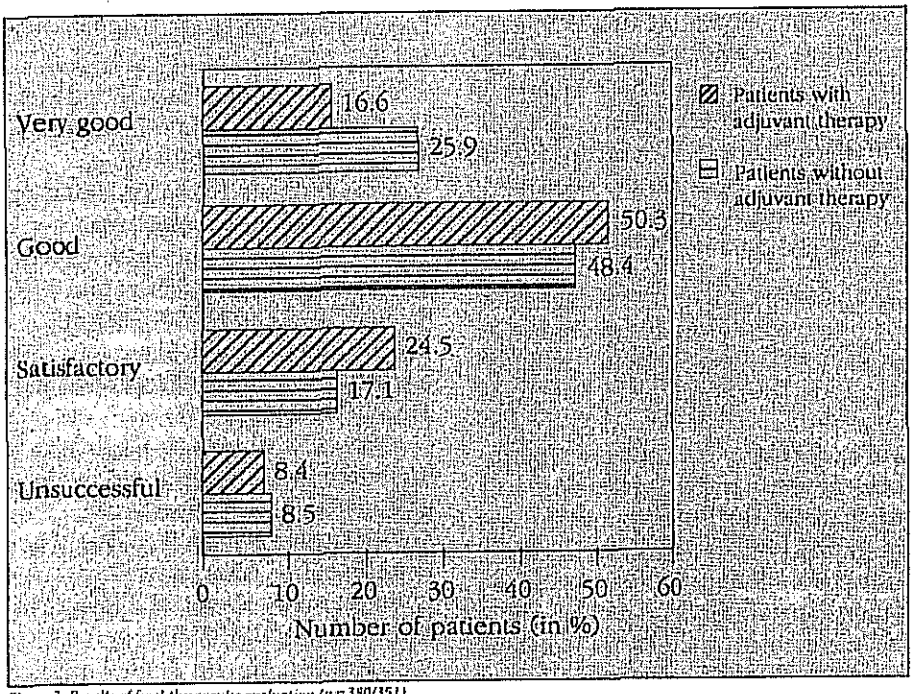

Figure 3: Results of final therapeutic evaluation (n=380/351)

Diagnostic Collective	Very good/ good	Satis-factory	Un-successful
Condition ensuing concussion of the brain (n = 34)	94.1	5.9	-
Nervous exhaustion (n = 114)	85.1	11.4	3.5
Neuralgia (n = 70)	84.3	14.3	1.4
Neurodystonia (n = 89)	80.9	13.5	5.6
State of agitation (n = 44)	79.6	13.6	6.8
Depression (n = 81)	71.6	17.3	11.1
Irretentiveness (n = 101)	65.4	25.7	8.9
Post-encephalitic condition (n = 7)	57.1	42.9	-
Arteriosclerosis (n = 17)	54.9	31.0	14.1
Parkinson's disease (n = 11)	54.6	36.3	9.1
Multiple sclerosis (n = 9)	33.3	66.7	-
Amyotrophic lateral sclerosis (n = 5)	20.0	60.0	20.0

Table 5: Therapeutic results (monotherapy) within individual diagnostic collectives (indicated in percent).

vestigation showed approximately 74 % of the monotherapy patients had been treated with either very good or good success. On comparing these findings with the therapeutic results obtained in patients having received supplementary therapy, no significant differences between the monotherapeutic patients and those with adjuvant treatment are determinable in regard to the quantity of successful treatments (Fig. 3).

Analysis of the therapeutic results achieved under monotherapy within the individual diagnostic groups proves good to very good therapeutic success was attainable in all twelve diagnostic collectives; although differences among certain individual groups were noted to exist here as well (Tab. 5).

Tolerance

Within a patient collective of 731 treated cases, the question as to the occurrence of undesired effects was answered "yes" in two instances. Thus the side-effect rate lies at 0.27 % and is to be designated as low. One of the reported cases concerned a 71-year-old female patient with arteriosclerosis who complained of agitation and difficulty in falling asleep during the second week of treatment. As Cerebrum compositum was thereupon discontinued, certain ascertainment cannot be made as to whether a causal link existed between the observed disturbance and the preparation's application. In the second case, a 39-year-old female patient reported redness and pruritus at the point of injection ensuing subcutaneous administration, with further complaint of increased salivation. This patient suffered from neurodystonia, irretentiveness, nervous exhaustion, and depression. Existence of a correlation between administration of Cerebrum compositum and the observed peculiarities was termed "possible" by the attending physician. Discontinuation of the preparation was unnecessary in this case; indeed, ensuing six weeks of therapy, a marked improvement in this patient's symptoms had been achieved. The described disturbances were reversible in both instances.

4. Discussion

This a.s. of Cerebrum compositum on 731 patients was performed with the objective of acquiring new knowledge as to manner of application, efficacy, and tolerance of the preparation as utilized within the physicians' daily practice. The findings of the investigation verify Cerebrum compositum's employment by prescribers in all of the applicative fields indicated under the Instructions for Use. Also substantiated was the therapeutic success attainable through this preparation for each of the listed indications. In keeping with the nature of a physician's general practice, indications such as arteriosclerosis, irretentiveness, nervous exhaustion, and neurodystonia constituted a larger proportion of cases than did symptom-complexes such as amyotrophic lateral sclerosis and multiple sclerosis for example, the therapies of which are generally entrusted to neurological specialists or specialized clinics due to the symptomatic severity and relatively unfavorable prognoses involved. Nevertheless, the cases docu-

mented within this a.s. suffice for fundamentally verifying utilization of Cerebrum compositum as being a justified measure, legitimate even in the therapy of syndromes such as these under certain circumstances.

Many of the patients participating in this a.s. were given multiple diagnoses. Here, application of combination-preparations such as Cerebrum compositum with its wide spectrum of action, for example, offers immense advantages to prescriber and patient alike. Employment of a combination-preparation with comprehensive efficacy also provides enormous simplification in the therapy- plans of syndromes displaying frequent alteration in symptoms (e.g. neurodystonia) as well as of those having pronounced daily fluctuation within their symptom complexes (e.g. depression).

The documented therapeutic results show Cerebrum compositum to be reliably effective in each of the asserted fields of application. Whether the preparation is employed in monotherapy or in combination with supplementary treatment (medicinal and/or physical) is unimportant. A phenomenon familiar to every physician of practical medicine is that one and the same diagnosis may apply to forms of pathological processes which are easily influenced (and which respond promptly and well to a single therapeutic measure), or to therapeutically resistant cases (difficult to control, even under application of multiple modes of treatment). Depending upon the particulars of the symptom picture in question (duration and severity of illness, accompanying affections, etc.), potentially unfavorable conditions may thus exist from the beginning, making employment of further medicinal agents unavoidable.

In addition to the effectiveness of a medication, a further factor always of great interest to those utilizing it is that of tolerance. The exceptional tolerance of Cerebrum compositum is illustrated within the framework of this a.s. in the form of the extremely low side-effect rate acquired. Due to their composition, homeopathic preparations generally exert no harmful effects on the organs of elimination or metabolic degradation within the human organism. This is extremely important for elderly patients in particular, who frequently suffer from impaired hepatic metabolism as well as reduced capabilities in renal elimination. In summary, the a.s. at hand has proven the homeopathic combination-preparation Cerebrum compositum to be not only a sensibly conceived, but a reliably effective and well-tolerated medication.

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