



M E D I C I N A   B I O L O G I C A

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## **Antihomotoxic Treatment of Chronic Sinusitis**

**Results of a Drug Monitoring Study  
with Euphorbium compositum S Injection  
Solution**

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# Antihomotoxic Treatment of Chronic Sinusitis

## Results of a Drug Monitoring Study with Euphorbium compositum S Injection Solution

### Abstract

The efficacy and tolerability of Euphorbium compositum S injection solution was investigated in the treatment of 557 patients, suffering from chronic sinusitis (n = 361), eustachian tubal catarrh (n = 132), middle-ear hydrops (n = 32) and other diseases (n = 43). 35% of the patients received Euphorbium compositum S as monotherapy. For 76% of the patients the time-point of first improvement of the symptoms was during the first 2 weeks of treatment. Including longer periods of treatment, symptom improvement was reported for 97%. Both, investigators and patients assessed the efficacy of the treatment (monotherapy or in combination with concomitant therapy), as very good or good in 87%-90% of the cases. The assessment of tolerability of the treatment was excellent or good in 98% of the patients.

**Key words:** Chronic sinusitis, eustachian tubal catarrh, middle-ear hydrops, drug monitoring study, Euphorbium compositum S Injection solution

### Introduction

Based on the fundamentals of the antihomotoxic therapy, Euphorbium compositum S injection solution principle of action is to counteract homotoxin-caused damage through balancing the disturbed body's regulatory mechanisms (1, 2). Effects on the immunosystem and antiviral processes have been shown for this remedy (3, 4, 5). As inadequate activation of the immunosystem may not only be a consequence, but also the cause of a chronic disease, antihomotoxic therapy seems to be a promising therapeutical tool. Chronic sinusitis nowadays is diagnosed with increasing frequency in children, adults and in the aged. It is recognized as a common clinical syndrome. Beside enhanced awareness, environmental influences and frequent respiratory tract infections in childhood are discussed as underlying causes. Standard therapy involves antibiotics, decongestants and corticosteroids (6, 7). The disease specific symptoms, like nasal obstruction, postnasal drip and intermittent facial pain may lead to a continuous feeling of general malaise.

The homeopathic remedy Euphorbium compositum S injection solution (manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden, Germany) is available for the treatment of chronic sinusitis (maxillary sinus, frontal sinus, and ethmoidal areas), eustachian tubal catarrh (eustachian salpingitis) and middle-ear hydrops for many years. It is a compositum-preparation and therefore contains various single-remedy medications (Euphorbium, Pulsatilla, Luffa operculata, Mercurius bijodatus, Mucosa nasalis suis, Hepar sulfuris, Argentum nitricum and Sinusitis-nosode). In addition to a drug monitoring study with Euphorbium com-

positum S drops, another investigation with identical methods and efficacy/tolerability parameters was performed with Euphorbium compositum S injection solution; its results are reported here.

### Methods

The data ascertained by the investigators comprised demographic data, disease/diagnosis, duration, possible pre-treatment and intensity of the disease, dosage regimen, possible additional medications or other therapies and duration of the therapy.

For the assessment of efficacy the following parameters were evaluated:

- time-point of first improvement of the symptoms
- assessment of the efficacy of the treatment by investigator and patient (scale: very good = no more complaints, good = significant improvement, moderate = slight improvement, without success = no change and deterioration).

Assessment variables for therapeutic tolerability were

- determination of possible side effects
- assessment of tolerability by the investigator (scale: excellent, good, moderate, bad)

The statistical analysis of the data was performed exploratively by calculating absolute and relative frequencies.

### Results

#### Patients

This drug monitoring study was performed in Germany with 557 patients. The attending doctors were general practitioners (51), ENT-specialists (12) and internists (3). The majority of patients were female

Indications	Time-point of first improvement of the symptoms							
	After the first application	After 1-3 days	After 4-7 days	After 1-2 weeks	After 2-4 weeks	More than 4 weeks	No improvement	Termination of treatment
Chronic sinusitis n = 361	4.4	14.7	22.4	26.6	19.1	8.6	3.6	0.3
Eustachian tubal catarrh n = 132	11.4	37.8	33.3	11.4	3.0	2.3	0.8	0.0
Middle-ear hydrops n = 32	3.1	59.4	15.6	12.5	6.3	0.0	3.1	0.0
Other diagnosis n = 43	16.3	34.9	11.6	13.9	16.3	7.0	0.0	0.0
All patients n = 557	7.0	24.4	23.2	21.5	14.4	6.5	2.7	0.2

Table 1: Time-point of first improvement of the symptoms. Percentage in the different indications and in the total patient population. Multiple assignment was possible.

(57%). Chronic sinusitis (64%) was the indication diagnosed most frequently, followed by eustachian tubal catarrh (23%), middle-ear hydrops (6%) and other diseases (7%). With regard to patients age, there was a trend to a higher number of patients included in the range of 31-60 years of age, compared to the young and to the aged.

Approximately half of the patients characterized the intensity of the specific symptoms as 'moderate' (49%). The ratings 'mild' and 'severe' were reported with similar frequencies (11% and 16%, respectively, no data available: 24%).

According to its character the pre-duration of the disease lasted from less than 3 days up to more than 5 years. Frequencies in the different time intervals were quite homogenous. In general, approximately half of the patients had a pre-duration of up to 4 weeks, whereas the others reported a longer period of pre-existence. In total, most of the patients (57%) had received a specific treatment, before they entered the investigation. Chronic sinusitis patients had a much higher pre-treatment rate (71% pre-treated vs. 29% untreated) compared to the other indications. In most cases, the pre-treatment was medical (64%). A combined treatment, medical and others (physical, surgery etc.) was documented for 34% of the patients. During medical pre-treatment, antibiotics/anti-infectives, anti-tussives/expectorants and rhinologics were the drugs most frequently taken.

### Treatment

The generally recommended dosage (3-1 ampoules/week) was sufficient for most of the patients (77%). An acute disorder dosage (daily injections) was necessary for 17%, and 6% received a combination of both. The investigators applied Euphorbium compositum S predominantly intramuscular (58%). Less frequencies were reported for a subcutaneous (21%), intravenous (10%), oral (3%) or combined (2%) modes of application. 35% of the patients were exclusively treated with Euphorbium compositum S as monotherapy, whereas 65% received further treatment in addition to the homeopathic. The kind of an additional therapy was medical (30%), physical (29%) or a combination of both (41%). As additional medical therapy rhinologics, homeopathics, immunotherapeutics, anti-phlogistics and antitussives/expectorants were preferred. Physical therapies were mainly inhalations, infrared and microwave radiation. For the majority of the patients (83%), the duration of the treatment lasted from 1 week to 2 months. In chronic sinusitis, the treatment duration most frequently reported was in the range of 2-4 weeks. The investigators did not change the dosage during treatment in 89% of the cases, whereas in 11% a dose reduction occurred.

### Efficacy parameters

Concerning the time point of first improvement it can be stated that during 2 weeks of treatment, 76% of the patients ex-

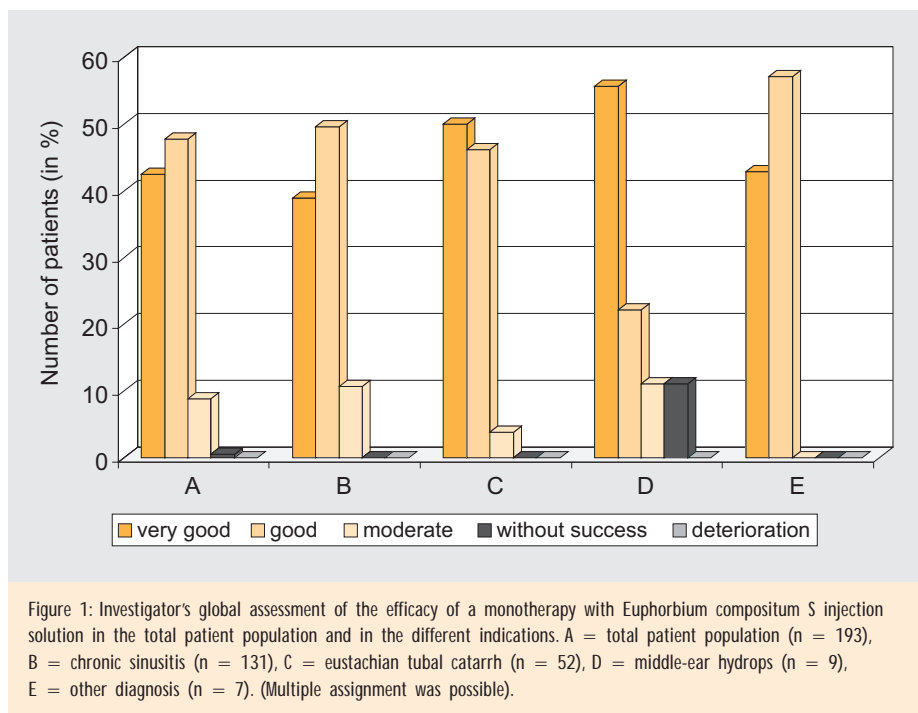
perienced alleviation of their complaints. The respective rate of improvement increased to 97% including longer periods of treatment. No improvement or a premature determination of the therapy was documented in 3% of the cases (Table 1).

The global assessment of the treatment by investigators and patients was ascertained for both, a monotherapy with Euphorbium compositum S and a combined therapy with additional medication/physical therapy. In each of the four evaluations the assessment of efficacy was very good or good in the range of 87%-90% and moderate in the range of 8%-11%. Generally, the results of the evaluations did not differ significantly. A monotherapy with Euphorbium compositum S was assessed even slightly better compared to a treatment including additional medication/physical therapy. The assessment 'without success' did not exceed 3% in any of the evaluations. No deterioration was observed in any case (Figure 1).

### Tolerability

557 patients were treated in this investigation. For n = 9 the tolerability was assessed as moderate. The rating 'bad' did not occur. Therefore, the assessment of tolerability of the treatment was excellent or good in 98% of the patients (excellent: 68%, good: 30%).

For 1 patient, who was treated for chronic sinusitis, an adverse event was reported. The patient had symptoms of burning (in-



tensity: moderate, duration: 3 days) and pain (intensity: mild, duration: 1 day) at the local site 2 days after injection. No special treatment for the symptoms was necessary. A relationship to the medication was assessed as unlikely. It was assumed that the injection itself caused the local reactions.

### Conclusion

Different approaches are possible in the treatment of chronic sinusitis, which is often caused by infection, allergies and vasomotor rhinitis/sinusitis. Pharmacological and non-pharmacological measures are used and often combined, depending on the different status of the disease (8).

With Euphorbium compositum S injection solution an antihomotoxic homeopathic remedy is available, for which excellent efficacy and tolerability results were obtained by various investigations and during the long-time availability on the market. The results of this drug monitoring study indicate a fast and intensive improvement of the diseases investigated: chronic sinusitis, eustachian tubal catarrh, middle-ear hydrops and other diseases, preferably of the upper respiratory tract. These results are in strong accordance with a further drug monitoring study, which was performed with Euphorbium compositum S drops with identical inves-

tigation methods. Euphorbium compositum S injection solution has therefore proven, in accordance with its tolerability to be a valuable and cost effective remedy in the treatment of the upper mentioned diseases.

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