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# HerbClip™



**FILE: ▪Lemon Balm (*Melissa officinalis*)**
**▪Valerian (*Valeriana officinalis*)**
**▪Sleep Disturbances**
**▪Motor Restlessness**

**HC 060563-319**

**Date: December 29, 2006**

**RE: Use of Valerian/Lemon Balm Extract in Children with Restlessness and Sleep Disorders**

Müller SF, Klement S. A combination of valerian and lemon balm is effective in the treatment of restlessness and dyssomnia in children. *Phytomed.* June 12, 2006;13(6):383-387.

Dyssomnia includes a variety of sleep disorders. Children with dyssomnia may have difficulty falling asleep, may wake up during the night, may have night terrors, or may walk in their sleep. Although these sleep disturbances might be temporary, up to 30% of children can suffer from them. Motor restlessness is another condition that affects children. Children with motor restlessness are unable to sit still and concentrate, particularly in situations that demand discipline and attention. General motor restlessness may be temporary, or it may be a personality characteristic that continues beyond childhood. Clinical studies have shown that the combination of valerian (*Valeriana officinalis*) and lemon balm (*Melissa officinalis*) improves sleep quality and mood in adults with sleep disorders. The purpose of this study was to evaluate the effectiveness and tolerability of valerian and lemon balm in children with motor restlessness and nervous dyskoimesis (sleep disturbance).

This open-label study was conducted at 207 pediatric clinics in Germany and included 938 children under the age of 12. Each child completed a baseline study visit that included a complete medical history, review of current diagnosis, and documentation of the incidence and severity of symptoms by the child's doctor. The child was instructed to take up to 4 tablets daily of Euvegal® forte (Schwabe Pharmaceuticals, Karlsruhe, Germany). Each tablet contains 160 mg valerian root extract and 80 mg lemon balm leaf extract. The child returned for the second and final study visit after taking Euvegal forte for about 4 weeks. At this visit, the child was examined, and the child's doctor recorded the incidence. The doctor assessed the tolerability of the product, and both the parent and the doctor completed questionnaires to evaluate the child's response to the product.

A total of 918 children were evaluated in the study. The average age of the children was 8.3 years. The mean duration of study participation was 31.9 days. The mean dosage was 3.5 tablets per day, and 74.6% of the children were given the maximum dose of 4 tablets per day. The percentage of children reporting daily symptoms fell from 61.7% at baseline to 12.5% after taking Euvegal forte for 4 weeks. The symptoms of restlessness and dyssomnia were rated as moderate or severe in the majority of children at baseline. At the final visit, restless and dyssomnia were rated as absent or mild in the majority of children. The majority of the parents and the doctors rated the efficacy of the product as "good." The doctors rated tolerability as "very good" or "good" for 96.7% of the children. Two adverse events of vomiting and urinary tract infection were reported, but neither was judged to be related to use of Euvegal forte.

The authors state that children taking the valerian and lemon balm combination for 4 weeks experienced fast and significant improvement of their symptoms. The authors conclude that Euvegal forte is well-tolerated and effective in the treatment of children with restlessness and dyssomnia. Current standard treatments for restlessness and dyssomnia in children are synthetic psychotropic drugs which may bear a high risk of addiction or side effects. The authors recommend conducting head-to-head comparison clinical studies of Euvegal forte with synthetic drugs in children to directly compare the safety and efficacy and to eventually provide an alternative with a better risk-benefit ratio. Although this study evaluated a large number of children, the results are limited because of its design as an open study. Thus, no statistical analysis is reported, there is no placebo or active control, and the children, parents, and investigators all knew what the children were taking.

*—Heather S. Oliff, PhD*

Enclosure: Referenced article reprinted with permission from Elsevier, GmbH.