



# EDCO FORUM<sup>®</sup>

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## SOMNOTE<sup>®</sup> CIV (CHLORAL HYDRATE CAPSULES, USP 500 MG)

### *Safe, Effective Treatment of Simple Insomnia*

About 60 million Americans suffer from insomnia each year. People with insomnia report that they cannot fall asleep or they cannot stay asleep. This can lead to serious sleep deficits and other health problems. Insomnia tends to increase with age and affects about 40% of women and 30% of men. The good news is that insomnia is highly treatable. Medication is the most common form of treatment for insomnia, with 25% of Americans taking some type of medication every year to help them sleep. Prescription medications that promote sleep are called hypnotics and they are the most effective sleep aids available. When used for short periods of time, these medications generally induce a reasonable sleep and reestablish a more normal sleep cycle. The oldest of these sleep-inducing medications is chloral hydrate.

**Breckenridge Pharmaceutical, Inc.** (Boca Raton, FL), markets **Somnote<sup>®</sup>**, the *only* soft gel capsule form of chloral hydrate available today. Somnote<sup>®</sup> is indicated for the short-term treatment of simple insomnia. Each capsule contains 500 mg chloral hydrate USP. Somnote<sup>®</sup> acts as a depressant on the central nervous system and at therapeutic doses (and without the introduction of alcohol and other depressants) is competent in promoting sleep and producing few negative side effects. Somnote<sup>®</sup> takes effect in a relatively short time (30 minutes) and will induce sleep in about an hour. The action of chloral hydrate is confined to the cerebral hemispheres. The drug is detoxified in the liver and subsequently eliminated by the kidney. Somnote<sup>®</sup> should be taken shortly after meals and should be taken with a full glass of a liquid such as water, fruit juice, or ginger ale. Somnote<sup>®</sup> may also be used as a routine sedative to relieve tension and anxiety. It has been used preoperatively or prior to electroencephalographic evaluation to allay anxiety and produce sedation or sleep. Somnote<sup>®</sup>, alone or in conjunction with Paraldehyde, is effective in preventing alcohol withdrawal symptoms and suppressing the syndrome once it develops. The drug may also be effective in reducing anxiety associated with the withdrawal of other drugs such as narcotics or barbiturates. While

Somnote<sup>®</sup> may be habit-forming, tolerance and addiction are uncommon. Somnote<sup>®</sup> has been found to lose much of its effectiveness for both inducing and maintaining sleep by the end of a 2-week period of drug administration.

The usual hypnotic dose of Somnote<sup>®</sup> for adults is 500 mg to 1 gram, 15-30 minutes before retiring. The usual sedative dosage for adults is 250 mg, 3 times daily after meals. When Somnote<sup>®</sup> is administered in the management of alcohol withdrawal symptoms, the usual dosage is 500 mg to 1 gram, repeated at 6-hour intervals if needed. Generally, single doses or daily dosage for adults should not exceed 2 grams.

William Kirk, MD, Medical Director of the Behavioral Health Service, Robert Packer Hospital (Sayre, PA), has been prescribing chloral hydrate for his patients for about 40 years. Dr. Kirk's main indication for prescribing Somnote<sup>®</sup> is initial insomnia—trouble falling asleep. "Approximately 80% of my patients have some sort of sleep disorder that might be contributing to the condition which I am treating, so I like to address their sleep issues early on. Somnote<sup>®</sup> is an effective sedative/hypnotic and is rather benign. It is relatively safe and gives pretty good rest if not taken in too high a dose. Chloral hydrate has been around for about 125 years and has all kinds of uses."

Somnote<sup>®</sup> is also frequently used as a hypnotic in the pediatric population. Chloral hydrate is a safe and effective agent that is often prescribed for short-term sedation as well as surgical and radiological premedication. According to Alejandro Chediak, MD, Assistant Professor of Medicine, University of Miami, and Chief Physician, Sleep Disorder Center, Mount Sinai Medical Center (Miami, FL), "there is a long track record for the use of chloral hydrate as a hypnotic in children. The benefit of using Somnote<sup>®</sup> in children is that it is relatively short-acting and is metabolized by the respiratory system. It is a fairly safe drug to use on children, with the exception of those who have lung disease or any kind of breathing disorder."

For children, the hypnotic dose of Somnote® is 50 mg per kg of body weight with a maximum single dose of 1 gram. The sedative dosage for children is 8 mg per kg of body weight 3 times a day, with a maximum dosage of 500 mg 3 times a day as a premedication for electroencephalogram evaluation. Children have been given chloral hydrate in a dosage of 20 to 25 mg per kg of body weight.

Misperceptions about sleep medicines—both prescription and nonprescription—seem to persist. Many prescription sleep medications, such as Somnote®, have been proven highly safe and effective. Chloral hydrate was introduced into therapeutics more than 120 years ago and soon became popular as a somnifacient. Studies have examined data on the effectiveness of hypnotics and have concluded that they are effective and reliable for shortening the time it takes to fall asleep, increasing total sleep time, decreasing the number of awakenings, and improving sleep quality.

**Contraindications:** Chloral hydrate is contraindicated in patients in marked hepatic or renal impairment and in patients who have previously demonstrated hypersensitivity or idiosyncratic reaction to the drug. **Warnings:** Chloral hydrate may be habit-forming. Chloral hydrate may increase the rate of metabolism of concomitantly administered Warfarin anticoagulants, thus reducing their effectiveness. Upon withdrawal of chloral hydrate, the rate of metabolism of the anticoagulant drug will decrease and its plasma level will rise with the possibility of the sudden increase of anticoagulant effects

(i.e., development of bleeding tendency and hemorrhage). *The prothrombin time of patients on anticoagulant therapy normally must be followed continually; however, when chloral hydrate is added to or subtracted from the therapeutic regimen, or when changes in dosage of chloral hydrate are contemplated, the effective of the sedative on prothrombin time deserves special attention.* **Adverse reactions:** gastric irritation manifested by nausea, vomiting and diarrhea is the most frequent side effect of oral chloral hydrate administration. This effect may be minimized by administering the capsule with a full glass of water or other liquid. There is no evidence in the published literature to support the claim that the complex chloral betaine causes less gastric irritation than does chloral hydrate. Residual sedation or “hang-over” occurs infrequently following usual hypnotic doses. Cutaneous reactions to chloral hydrate are not common but have included scarlatiniform or erythematous rash, urticaria, angioedema, purpura, eczema, bullous lesions, and erythema multiforme. Sometimes these cutaneous reactions have been accompanied by fever; ataxia and dizziness have also occurred. Rarely, a somnambulistic reaction characterized by disorientation and incoherence has been reported.

\* Chloral hydrate is a schedule IV drug. Patients should be warned that chloral hydrate may impair ability to perform hazardous activities requiring mental alertness or physical coordination such as operating machinery or driving a motor vehicle. Patients should be cautioned against taking chloral hydrate with other depressant drugs, including alcohol.

## About Breckenridge Pharmaceutical, Inc.

Breckenridge Pharmaceutical, Inc. is a privately held pharmaceutical marketing, research and development company that was founded in 1983. Breckenridge markets a broad range of Branded and Generic prescription products in many therapeutic categories including the Somnote® brand of chloral hydrate capsules. The company has introduced over 30 new products in 2003 and plans to introduce many more in 2004. Breckenridge Pharmaceutical, Inc. has an experienced sales team that reaches all major customer classes of trade including: Wholesalers, Distributors, Chains, and Managed Care.



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For more information about Somnote® CIV or other Breckenridge products, visit the company's Web site at [www.bpirx.com](http://www.bpirx.com); or visit a company representative at booth #971 at the Annual Meeting of the American Psychiatric Association, May 1–6, New York, New York; or booth #349, at the Associated Professional Sleep Societies Annual Meeting, June 5–10, Philadelphia, Pennsylvania.