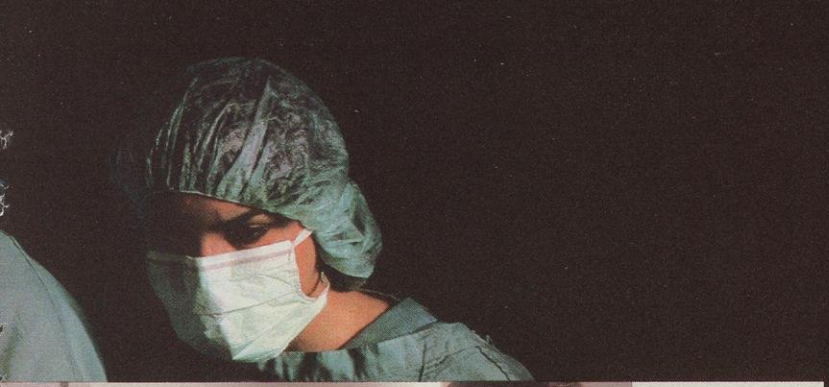
Dalmane advertisement.

[s.l.]: [s.n.], 1984



Contemporary Hypnotic Therapy '83

that follow

First-night efficacy—with few reports of morning hangover

In objective sleep laboratory studies, Dalmane proved effective from the first night on. Sleep latency decreased significantly on the first night of therapy ($p < 0.2$), and total sleep time increased significantly ($p < 0.2$). And in clinical studies involving 2010 patients, Dalmane also decreased sleep induction time and increased sleep duration on the first night by a significant margin ($p < 0.05$).[3]

Moreover, there were few complaints of morning hangover by any of the 107 surgical patients given Dalmane (flurazepam HCl/Roche) 30 mg for seven consecutive nights in clinical studies.[1,2]

Avoids rebound insomnia upon discontinuation

Rebound insomnia—a statistically significant worsening of insomnia beyond baseline levels after discontinuation of therapy—has not been reported with Dalmane.[4] Thus, with Dalmane therapy, you can be assured of a relatively problem-free discontinuation. (Caution patients about driving or drinking alcohol after ingesting the drug.)

Compatible with warfarin therapy and no chemical interference with most routine laboratory tests

An important advantage for patients on warfarin anticoagulant therapy: Dalmane does not cause an unacceptable fluctuation in prothrombin time.[3] And Dalmane does not cause chemical interference with the results of 22 common laboratory tests—including SGOT, BUN, glucose, total protein and creatinine, among others.[3] Alterations due to pharmacological interference have been reported. (See Adverse Reactions in summary of complete product information.) Dalmane is contraindicated in patients who are pregnant or hypersensitive to the drug.

References: 1. Meyer JA, Kurland KZ: *Milit Med 138*:471-474, Aug 1973. **2.** Feffer HL, Gibbons B: *Med Times 101*(8):130-135, Aug 1973. **3.** Data on file, Hoffmann-La Roche Inc., Nutley, NJ. **4.** Monti JM: *Methods Find Exp Clin Pharmacol 3*:303-326, May 1981.

For restful nights throughout therapy

Dalmane® (IV)

flurazepam HCl/Roche

15-mg/30-mg capsules

stands apart

See next page for a summary of product information.

Dalmane® ℞

(flurazepam HCl/Roche)
15-mg and 30-mg capsules

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; in acute or chronic medical situations requiring restful sleep. Objective sleep laboratory data have shown effectiveness for at least 28 consecutive nights of administration. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended. Repeated therapy should only be undertaken with appropriate patient evaluation.

Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, *e.g.*, excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. *Adults:* 30 mg usual dosage; 15 mg may suffice in some patients. *Elderly or debilitated patients:* 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.

ROCHE®

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Manati, Puerto Rico 00701