EFFECTIVE, LOW-DOSE THERAPY TO HELP PATIENTS FALL ASLEEP GENTLY
Restoril® 7.5 mg capsules
(temazepam) IV

FOR TRANSIENT AND SHORT-TERM INSOMNIA (GENERALLY 7–10 DAYS’ THERAPY)*

▼ More than a decade of established RESTORIL® safety

• Essentially no hangover effects1-3
• Low potential for rebound insomnia4 or memory loss
• No evidence of tolerance development found after at least two weeks of nightly use (based on sleep laboratory study results)
• Virtually no daytime anxiety or G.I. upset

▼ Induces sleep as effectively as RESTORIL (temazepam) 15 mg5

▼ Allows titration for greater flexibility and control†

RESTORIL therapy is contraindicated in pregnant women.

* As with all benzodiazepines, patients should be evaluated for the emergence of any abnormal thinking or behavioral changes, with appropriate consideration given to all possibilities.
† Also available in 15 mg and 30 mg capsules.
The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. If Restoril® (temazepam) is to be combined with other drugs having known hypnentic properties or CNS-depressant effects, consideration should be given to potential additive effects.

The possibility of a synergistic effect exists with the co-administration of Restoril® (temazepam) and diphenhydramine. One case of stillbirth at term has been reported 8 hours after a pregnant patient received Restoril® (temazepam) and diphenhydramine. A cause and effect relationship has not yet been determined. (See CONTRAINDICATIONS)

Information for Patients
Please consult package insert for full prescribing information.

Laboratory Tests
The usual precautions should be observed in patients with impaired renal or hepatic function and in patients with chronic pulmonary insufficiency. Abnormal liver function tests as well as blood dyscrasias have been reported with benzodiazepines.

Drug Interactions
The pharmacokinetic profile of temazepam does not appear to be altered by orally administered cinemidine doses as labeled.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity studies were conducted in rats at dietary temazepam doses up to 150 mg/kg/day for 24 months and in mice at dietary dose of 160 mg/kg/day for 18 months. No evidence of carcinogenicity was observed although hyperplastic liver nodules were observed in female mice exposed to the highest dose. The clinical significance of this finding is not known.

Fertility in male and female rats was not adversely affected by Restoril® (temazepam). No mutagenity tests have been done with temazepam.

Pregnancy
Pregnancy Category X (see CONTRAINDICATIONS).

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Restoril® (temazepam) is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in children below the age of 18 years have not been established.

ADVERSE REACTIONS
During controlled clinical studies in which 1076 patients received Restoril® (temazepam) at bedtime, the drug was well tolerated. Side effects were usually mild and transient. Adverse reactions occurring in 1% or more of patients are presented in the following table:

<table>
<thead>
<tr>
<th>Drug</th>
<th>% Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>(n=1076)</td>
</tr>
<tr>
<td>n=783)</td>
<td></td>
</tr>
<tr>
<td>Drowsiness</td>
<td>9.4</td>
</tr>
<tr>
<td>Headache</td>
<td>8.6</td>
</tr>
<tr>
<td>Fatigue</td>
<td>7.3</td>
</tr>
<tr>
<td>Nervousness</td>
<td>4.6</td>
</tr>
<tr>
<td>Lethargy</td>
<td>4.3</td>
</tr>
<tr>
<td>Dizziness</td>
<td>4.3</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.1</td>
</tr>
<tr>
<td>Hangover</td>
<td>1.5</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.1</td>
</tr>
<tr>
<td>Depression</td>
<td>1.8</td>
</tr>
<tr>
<td>Dry Mouth</td>
<td>1.7</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1.7</td>
</tr>
<tr>
<td>Abdominal Discomfort</td>
<td>1.5</td>
</tr>
<tr>
<td>Euphoria</td>
<td>1.5</td>
</tr>
<tr>
<td>Weakness</td>
<td>0.9</td>
</tr>
<tr>
<td>Confusion</td>
<td>0.3</td>
</tr>
<tr>
<td>Blurred Vision</td>
<td>0.3</td>
</tr>
<tr>
<td>Nightmares</td>
<td>1.2</td>
</tr>
<tr>
<td>Vertigo</td>
<td>0.4</td>
</tr>
</tbody>
</table>

The following adverse events have been reported less frequently (0.5-0.9%):
- Central Nervous System - anorexia, ataxia, equilibrium loss, tremor, increased dreaming
- Cardiovascular - palpitations
- Gastrointestinal - vomiting
- Musculoskeletal - backache, Special Senses - hypotension, burning eyes
- Amnesia, hallucinations, horizontal nystagmus, and paradoxical reactions including restlessness, oversedation, and agitation were rare (less than 0.5%).

SANDOZ PHARMACEUTICALS CORPORATION
East Hanover, New Jersey 07936

(REV: OCTOBER, 1992 RES-215)

REFERENCES

SANDOZ PHARMACEUTICALS CORPORATION
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DORSEY PHARMACEUTICALS CORPORATION
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INFORMATION FOR AUTHORS

The *Journal of the American Board of Family Practice* welcomes for editorial review manuscripts that contribute to family practice as a clinical scientific discipline. High priority is given to reports of clinically relevant studies that have practical implications for improved patient care. Manuscripts are considered in relation to the extent to which they represent original work, their significance to the advancement of family medicine, and their interest to the practicing family physician. Some papers that are accepted by the *Journal* will be selected for an accompanying guest editorial or concurrent commentary by other invited authors addressing issues raised by the papers. The *Journal* publishes the following features:

**Original Articles.** Reports of original research, usually dealing with a clinical, health services, or other clinically relevant study.

**Medical Practice.** Scholarly articles that relate directly to clinical topics useful in everyday family practice, whether dealing with diagnostic or therapeutic roles of the family physician or reporting studies of what family physicians do in practice.

**Clinical Review.** In-depth reviews of specific clinical problems, disease entities, or treatment modalities; comprehensive and critical analysis of the literature is required (usual maximum length 5000 words).

**Clinical Guidelines and Primary Care.** Summaries of major clinical guidelines prepared by various specialty, governmental, or health care organizations, with critical commentary from a primary care perspective.

**Family Practice and the Health Care System.** Articles reporting studies and scholarly commentary on changing trends and patterns of care in family practice, primary care, and the health care system.

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**Brief Reports.** Short reports of pilot studies or case reports with a teaching point of clinical relevance (usual length 1000–1500 words).

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**Reflections in Family Practice.** Papers in narrative or essay format that illuminate qualitative aspects of family practice, including such areas as ethical issues, the physician-patient relationship, or the diverse roles of the family physician.

**Editorial.** Focused opinion or commentary that bears on an issue relevant to the field. May or may not accompany an original article in the same issue (usual length 1000–1500 words).

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**Book Reviews.** Books for review and book reviews should be sent to Dr. John P. Geyman, Editor, the *Journal of the American Board of Family Practice*, Department of Family Medicine (HQ-30), School of Medicine, University of Washington, Seattle, WA 98195. The following guidelines are in accordance with the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." The current (fourth) edition was published in the February 7, 1991, issue of the *New England Journal of Medicine.*

**MANUSCRIPT SUBMISSION**

Manuscripts containing original material are accepted for consideration with the understanding that neither the author nor any part of its essential substance, tables, or figures has been or will be published or submitted for publication elsewhere before appearing in the *Journal.* This restriction does not apply to abstracts or press reports published in connection with scientific meetings. Copies of any possibly duplicative manuscripts should be submitted to the Editor along with the manuscript that is to be considered by the *Journal.* The *Journal* strongly discourages the submission of more than one article dealing with related aspects of the same study. In almost all cases, a single study is best reported in a single paper.

Submit an original and 3 copies of the complete manuscript, including text pages, legends, tables, references, and glossy prints of figures. Only typed copy on standard-sized typewriter paper and double-spaced throughout, with margins of at least 2.5 cm, is acceptable. Address all submissions to John P. Geyman, M.D., Editor, the *Journal of the American Board of Family Practice*, Department of Family Medicine (HQ-30), School of Medicine, University of Washington, Seattle, WA 98195. A covering letter should identify the person (with the address and telephone number) responsible for negotiations concerning the manuscript; the letter should make it clear that the final manuscript has been seen and approved by all authors. If authors acknowledge by name persons who provided important technical, advisory, or reviewer contributions, the corresponding author should sign the following statement: "I have obtained written permission from all persons named in the acknowledgment."

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Except for units of measurement, abbreviations are discouraged. Consult the Council of Biology Editors Style Manual (Fifth edition. Bethesda, MD: Council of Biology Editors, 1983) for lists of standard abbreviations. The first time an abbreviation appears, it should be preceded by the words for which it stands.

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Generic names should, in general, be used. If an author so desires, brand names may be inserted in parentheses.

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Sex bias should be avoided and gender-inclusive language used whenever possible.

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(List all authors, but if the number exceeds 6, give 6 followed by et al. Note that month and issue number are omitted when a journal has continuous pagination throughout a volume.)


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