Restoril (temazepam) - Drug Summary

Mallinckrodt, Inc.

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Restoril
(temazepam)

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Insomnia

Short-Term Treatment (Generally 7 to 10 Days):
Usual: 15mg before retiring
7.5mg may be sufficient for some patients and others may need 30mg

Transient Insomnia:
7.5mg before retiring

DOSING CONSIDERATIONS

Elderly
Elderly/Debilitated Patients:
Initial: 7.5mg before retiring

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: 7.5mg, 15mg, 22.5mg, 30mg

CONTRAINDICATIONS

Women who are or may become pregnant.

WARNINGS/PRECAUTIONS

Initiate only after careful evaluation; failure of insomnia to remit after 7-10 days of treatment may indicate primary psychiatric and/or medical illness. Worsening of insomnia and emergence of thinking or behavior abnormalities may occur, especially in elderly; use lowest possible effective dose. Behavioral changes (eg, decreased inhibition, bizarre behavior, agitation, hallucinations, depersonalization) and complex behavior (eg, sleep-driving) reported; strongly consider discontinuation if sleep-driving episode occurs. Amnesia and other neuropsychiatric symptoms may occur unpredictably. Worsening of depression, including suicidal thinking, reported. Withdrawal symptoms may occur after abrupt discontinuation. Rare cases of angioedema and anaphylaxis reported; do not rechallenge. Oversedation, confusion, and/or ataxia may develop w/ large doses in elderly and debilitated patients. Caution w/ hepatic/renal impairment, chronic pulmonary insufficiency, debilitated, severe or latent depression, and in elderly. Abnormal LFTs, renal function tests, and blood dyscrasias reported.

ADVERSE REACTIONS

Drowsiness, headache, fatigue, nervousness, lethargy, dizziness, nausea.

DRUG INTERACTIONS

Increased risk of complex behaviors w/ alcohol and CNS depressants. Potential additive effects w/ hypnotics and CNS depressants. Possible synergistic effect w/ diphenhydramine.

PREGNANCY AND LACTATION

Category X, caution in nursing.

MECHANISM OF ACTION

Benzodiazepine hypnotic agent.

PHARMACOKINETICS

Absorption: Well-absorbed; C_{max}=865ng/mL; T_{max}=1.5 hrs. **Distribution:** Plasma protein binding (96% unchanged); crosses placenta. **Metabolism:** Complete; conjugation. **Elimination:** Urine (80-90%); $T_{1/2}$=3.5-18.4 hrs.

ASSESSMENT

Assess for physical and/or psychiatric disorder, medical illness, severe or latent depression, renal/hepatic dysfunction, chronic pulmonary insufficiency, pregnancy/nursing status, alcohol use, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of withdrawal, tolerance, abuse, dependence, abnormal thinking, behavioral changes, agitation, depersonalization, hallucinations, complex behaviors, amnesia, anxiety, neuropsychiatric symptoms, worsening of depression, suicidal thoughts and actions, angioedema, driving/psychomotor impairment, worsening of insomnia, thinking or behavioral abnormalities, and possible abuse/dependence.

PATIENT COUNSELING

Inform about the benefits and risks of treatment. Instruct patient to take as prescribed. Inform about the risks and possibility of physical/psychological dependence, memory problems, and complex behaviors (eg, sleep-driving). Caution against hazardous tasks (eg, operating machinery/driving). Advise not to drink alcohol. Instruct to notify physician if pregnant/planning to become pregnant.

STORAGE

20-25°C (68-77°F).

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