

NEXTRIL 50/100

For The Use of a Psychiatrist Only

Abbreviated Prescribing information for NEXTRIL 50/100 (Tofisopam 50mg and 100mg tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Tofisopam is short-acting, weak anxiolytic with a wide therapeutic index. Tofisopam can effectively treat vegetative symptoms, fatigue and apathy associated with anxiety. Unlike other benzodiazepines, tofisopam has no hypnotic sedative, muscle relaxant and anticonvulsant effects and does not impair psychomotor, cognitive and memory function, also has mildly stimulating effect.

INDICATIONS: For the treatment of anxiety and depression.

DOSAGE AND ADMINISTRATION: It is essential to determine the dosage individually and it depends on the patient, the severity of the disease, and the tolerance of the drug. A typical dosage for adults is: 50mg to 100mg 1 to 3 times per day (a total of from 50 to 300 mg per day). Not indicated for children and adolescents under 18 years of age.

CONTRAINDICATION: In patients with hypersensitivity to benzodiazepines or other or any of the other substances of tablet, decompensated respiratory insufficiency, sleep apnea history and coma history. Concomitant administration tofisopam with tacrolimus, sirolimus and cyclosporine is contraindicated.

WARNINGS & PRECAUTIONS: Not recommended during the first trimester pregnancy and during lactation. Exercise caution while use in case of non-decompensated chronic respiratory insufficiency or in patients with a history of acute respiratory insufficiency, treatment of elderly and mentally ill patients or patients with kidney or liver disease and organic disorders of brain (e.g. atherosclerosis). Tofisopam may potentiate effect of other CNS depressants and is not recommended for chronic psychosis, and obsessive compulsive phobic disorders as it may increase the risk of suicide or aggressive behavior. Risk of seizures in epileptic patients. Not recommended for narrow-angle glaucoma patients.

DRUG INTERACTIONS: Interacts with metabolic inducers (alcohol, nicotine, barbiturates, antiepileptics, etc.), ketoconazole, itraconazole, some antihypertensives (clonidine, calcium channel blockers), digoxin, warfarin, disulfiram, antacids (cimetidine and omeprazole), oral contraceptives and alcohol.

ADVERSE REACTIONS: loss of appetite, confusion, restlessness, irritability, tension, headache, insomnia, respiratory depression, vomiting, nausea, constipation, flatulence, dry mouth, cholestatic jaundice, rash, scarlatiniform rash, itching, rash, muscle tension and muscle aches.

MARKETED BY:

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(Additional information is available on request)