

TANCODEP 2

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TANCODEP 2 [Imipramine Hydrochloride I.P. 25 mg, Diazepam I.P. 2 mg Tablet] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Imipramine:* Tricyclic antidepressant. Noradrenaline (NA) and serotonin (5HT) re-uptake inhibitor. *Diazepam:* Diazepam is a benzodiazepine that exerts anxiolytic, sedative, muscle-relaxant, anticonvulsant and amnestic effects.

INDICATION: Depression with co-morbid anxiety.

DOSAGE AND ADMINISTRATION: Dosage should be individualized for maximum beneficial effect. Up to eight tablets in divided dose may be given based on therapeutic response in adult patients. *For Geriatric patient* do not give more than two tablets daily. *For Pediatric patient* do not increase more than four tablets daily.

CONTRAINDICATION: *Imipramine:* use with monoamine oxidase inhibitors (MAOIs); myocardial infarction; hypersensitivity to tricyclic antidepressants; *Diazepam:* myasthenia gravis; severe respiratory insufficiency; severe hepatic insufficiency; sleep apnea syndrome; hypersensitivity to diazepam; acute narrow-angle glaucoma; pediatric patients under 6 months.

WARNINGS & PRECAUTIONS: *Imipramine:* Clinical worsening and suicide risk; underlying bipolar disorder; serotonin syndrome; angle closure glaucoma; *Diazepam:* psychotic patients; history of alcohol/drug abuse; chronic respiratory insufficiency. Pregnant patient. Potential for abuse and dependence,

DRUG INTERACTIONS: *Imipramine:* Drugs metabolized by P450 2D6; anti-cholinergic drugs; decongestants and local anesthetics containing sympathomimetic amine; drugs which lowers blood pressure; CNS depressant drugs. *Diazepam:* Centrally acting agents; alcohol which may enhance the therapeutic effect of the diazepam; antacids; drugs affecting cytochrome P450 3A and 2C19; phenytoin.

ADVERSE REACTIONS: *Imipramine:* orthostatic hypotension, hypertension, tachycardia, palpitation, myocardial infarction, arrhythmias, heart block, ECG changes, stroke, confusional states (especially in the elderly) with hallucinations, disorientation, delusions; anxiety, restlessness, agitation; insomnia and nightmares; hypomania; exacerbation of psychosis, paresthesias of extremities; incoordination, ataxia, tremors; peripheral neuropathy; extrapyramidal symptoms; seizures, alterations in EEG patterns; tinnitus, dry mouth, and, rarely, associated sublingual adenitis; blurred vision, disturbances of accommodation, mydriasis; constipation, paralytic ileus; urinary retention, dilation of the urinary tract, skin rash, urticaria, photosensitization; edema (general or of face and tongue); cross-sensitivity with desipramine, bone marrow depression, nausea, vomiting, diarrhea; peculiar taste, stomatitis, abdominal cramps, black tongue, gynecomastia in the male; breast enlargement and galactorrhea in the female; impotence; testicular swelling; elevation or depression of blood sugar levels; ADH secretion syndrome, jaundice (simulating obstructive); weight gain or loss; perspiration; flushing; urinary frequency; drowsiness, dizziness, weakness and fatigue; headache; parotid swelling; alopecia; proneness to falling, withdrawal symptoms, angle-closure glaucoma. *Diazepam:* confusion, dysarthria, headache, slurred speech, tremor, vertigo, constipation, gastrointestinal disturbances, diplopia, dizziness, hypotension, stimulation, restlessness, acute hyperexcited states, anxiety, agitation, aggressiveness, irritability, hallucinations, delusions, increased muscle spasticity, insomnia, sleep disturbances, and nightmares, behavioral effects, incontinence, urinary retention, skin reactions, changes in salivation, including dry mouth, hypersalivation, amnesia, neutropenia, , abuse and dependency and hypersensitivity reactions.

MARKETED BY:



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(Additional information is available on request)