AMAZEO

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

Abbreviated Prescribing information for AMAZEO [Amisulpride Tablets 50 mg,100 mg, 200 mg, 300 mg & 400 mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Amisulpride binds selectively to the human dopaminergic D2 and D3 receptor subtypes without any affinity for D1, D4 and D5 receptor subtypes.

INDICATION: For acute and chronic schizophrenic disorders, in which positive and negative symptoms are prominent, including patients characterised by predominant negative symptoms.

DOSAGE AND ADMINISTRATION: Acute psychotic episodes, oral doses between 400mg to 1200mg daily. Doses should preferably be administered before meal. For patients characterised by predominant negative symptoms, oral doses between 50 mg/d and 300 mg/d are recommended (higher doses should be administered BID). Renal insufficiency dose should be halved in creatinine clearance of 30-60mil/min and reduced to third in patients with 10-30ml/min. Elderly patients use with cautions due to possible risk of hypotension/sedation.

CONTRAINDICATION: Hypersensitivity to the active ingredient or to other ingredients of the product; concomitant prolactin-dependent tumours e.g. pituitary gland prolactinomas and breast cancer; phaeochromocytoma; children up to puberty; combination with levodopa; lactation.

WARNINGS & PRECAUTIONS: Hyperthermia; NMS; risk factors for diabetes; renal insufficiency; seizure; elderly patients; parkinsonism patients; abrupt discontinuation; involuntary movement disorders; QT interval prolongation; stroke; increased mortality in elderly patients with dementia related psychosis; venous thromboembolism; pregnancy; women of childbearing potential.

DRUG INTERACTIONS: Alcohol; CNS depressants including narcotics, anaesthetics, analgesics, sedative H1 antihistamines, barbiturates, benzodiazepines and other anxiolytic drugs, clonidine and derivatives; Antihypertensive drugs and other hypotensive medications; Drugs causing QT-prolongation { class IA antiarrhythmics (e.g., quinidine, disopyramide) and class III antiarrhythmics (e.g., amiodarone, sotalol), some antihistaminics, some other antipsychotics and some antimalarials (e.g., mefloquine}; drugs causing electrolyte imbalance.

ADVERSE REACTIONS: Reversible dose related extrapyramidal symptoms (tremor, rigidity, hypokinesia, hypersalivation, akathisia, dyskinesia), acute dystonia (spasm torticollis, oculogyric crisis, trismus), somnolence, tardive dyskinesia, insomnia, anxiety, agitation, orgasmic dysfunction, constipation, nausea, vomiting, dry mouth, galactorrhoea, amenorrhoea, gynaecomastia, breast pain, erectile dysfunction, hyperglycemia, bradycardia, hypotension, weight gain, elevations of hepatic enzymes, mainly transaminases, allergic reaction, neuroleptic malignant syndrome, QT interval prolongation, torsade de pointes, ventricular arrhythmias, fibrillation or cardiac arrest, sudden death, venous thromboembolism (PE/DVT), angioedema, urticaria, drug withdrawal syndrome neonatal.

MARKETED BY:

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IN/AMAZEO 50,100,200,300,400mg/Jun-15/01/AbPI

(Additional information is available on request)