

## AMAZEO OD

### For the use of a Psychiatrist or a Hospital only

Abbreviated Prescribing information for Amazeo OD (Amisulpride Sustained Release Tablets 100, 200 & 400 mg) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Amisulpride binds selectively to the human dopaminergic D2 and D3 receptor subtypes and produces antipsychotic effect through post-synaptic dopamine receptor blockade located in the limbic areas.

**INDICATION:** It is indicated for the treatment of acute and chronic schizophrenic disorders, with positive symptoms and/or negative symptoms, including patients characterized by predominant negative symptoms.

**DOSAGE AND ADMINISTRATION:** It should be administered once daily. For acute psychotic episodes, oral doses between 400mg/d and 800mg/d are recommended. In individual cases, the daily dose may be increased up to 1200 mg/d. Amazeo OD Tablets should be swallowed whole and not split, chewed or crushed.

**CONTRAINDICATION:** Amazeo OD is contraindicated in patients with prolactin-dependent tumors, phaeochromocytoma, and children up to 15 years of age, pregnancy, lactation, concomitant use of levodopa and medicine which may cause torsades de points and ventricular arrhythmias. It is also contraindicated in patients with hypersensitivity to the active ingredient or to other ingredients of the product.

**WARNINGS & PRECAUTIONS:** It may cause neuroleptic malignant syndrome. In patients with renal insufficiency or renal dialysis, the dose should be decreased. It may lower the seizure threshold, hence close monitoring is required. In elderly patients, patients with Parkinson's disease and cardiovascular disorders, the caution should be exercised. Gradual withdrawal of amisulpride is advisable to avoid withdrawal syndrome. Due to the lack of data; it should be used with caution in patients with moderate or severe hepatic impairment.

**DRUG INTERACTION:** The use of the following drugs is contraindicated: Class Ia, III antiarrhythmic agents and other medications such as cisapride, intravenous erythromycin, pentamidine. Calcium channel blockers (diltiazem, verapamil), beta-blockers such as clonidine and digitalis and Neuroleptics such as pimozide, haloperidol, Imipramine antidepressants, and lithium. Drugs causing hypokalemia such as diuretics, stimulant laxatives, intravenous amphotericin B, glucocorticoids, and tetracosactides are also contraindicated. Amisulpride may enhance the effects of the drugs such as CNS depressants including narcotics, anaesthetics, analgesics, sedative H1-antihistamines, barbiturates, benzodiazepines, clonidine and derivatives and other anxiolytic and antihypertensive and other hypotensive medications.

**ADVERSE REACTIONS:** Galactorrhoea, amenorrhoea, gynaecomastia, breast pain, orgasmic dysfunction and impotence, acute dystonia, extrapyramidal symptoms, insomnia, anxiety, agitation, somnolence, gastrointestinal disorders such as constipation, nausea, vomiting and dry mouth. Increased in plasma prolactin levels, weight gain, hypersalivation and akathisia. Hypotension and bradycardia have been reported occasionally.

### MARKETED BY:



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(Additional information is available on request)