

## AMAZEO OD

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

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

#### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** Amisulpride binds selectively with a high affinity to human dopaminergic D2/D3 receptor subtypes whereas it is devoid of affinity for D1, D4 and D5 receptor subtypes. Unlike classical and atypical neuroleptics, amisulpride has no affinity for serotonin,  $\alpha$ -adrenergic, histamine H1 and cholinergic receptors. In addition, amisulpride does not bind to sigma sites. At low doses it preferentially blocks pre-synaptic D2/D3 receptors, producing dopamine release responsible for its disinhibitory effects. This atypical pharmacological profile may explain amisulpride's antipsychotic effect at higher doses through post-synaptic dopamine receptor blockade and its efficacy against negative symptoms, at lower doses, through pre-synaptic dopamine receptor blockade.

**INDICATIONS:** Amisulpride SR is indicated for the treatment of acute and chronic schizophrenic disorders, with positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal), including patients characterised by predominant negative symptoms.

**DOSAGE AND ADMINISTRATION:** For acute psychotic episodes, oral doses between 400 mg/day and 800 mg/day are recommended. In individual cases, the daily dose may be increased up to 1200 mg/day. Doses above 1200 mg/day have not been extensively evaluated for safety and therefore should not be used. For patients with mixed positive and negative symptoms, doses should be adjusted to obtain optimal control of positive symptoms. Maintenance treatment should be established individually with the minimally effective dose. For patients characterized by predominant negative symptoms, oral doses between 50 mg/day and 300 mg/day are recommended. Amisulpride can be administered once daily at oral doses up to 400 mg, higher doses should be split into two separate doses.

**CONTRAINDICATION:** •Hypersensitivity to the active substance or to any of the excipients. •Concomitant prolactin-dependent tumours (e.g. pituitary gland prolactinomas or breast cancer. •Pheochromocytoma. •Children up to puberty. •Combination with levodopa.

**WARNINGS & PRECAUTIONS:** If a patient develops signs and symptoms indicative of Neuroleptic Malignant Syndrome (NMS) or presents with unexplained hyperthermia, particularly at high daily doses, all antipsychotic drugs including Amisulpride should be discontinued. Rhabdomyolysis has also been reported in patients without NMS. In cases of renal insufficiency, the dose should be decreased, or intermittent treatment could be considered. Severe liver toxicity has been reported with amisulpride use. In elderly patients, amisulpride, like other neuroleptics, should be used with particular caution because of a possible risk of hypotension or sedation. Caution should be exercised when amisulpride is prescribed in patients with known cardiovascular disease or family history of QT prolongation and concomitant use with neuroleptics should be avoided. Amisulpride should be used with caution in patients with stroke risk factors.

**DRUG INTERACTIONS:** Levodopa: reciprocal antagonism of effects between levodopa and neuroleptics. Amisulpride may enhance the central effects of alcohol. CNS depressants including narcotics, anaesthetics, analgesics, sedative H1 antihistamines, barbiturates, benzodiazepines and other anxiolytic drugs, clonidine, and derivatives combinations should be considered safely. Co-administration of amisulpride and clozapine may lead to an increase in plasma levels of amisulpride. Caution is advised when prescribing amisulpride with medicines known to prolong the QT interval, e.g., class IA antiarrhythmics (e.g. quinidine, disopyramide) and class III antiarrhythmics (e.g. amiodarone, sotalol), some antihistaminics, some other antipsychotics and antimalarials (e.g. mefloquine). Amisulpride may oppose the effect of dopamine agonists e.g. bromocriptine, ropinirole.

**ADVERSE REACTIONS:** Leukopenia, agranulocytosis, allergic reaction, galactorrhoea, prolactinoma, hyperglycaemia, hyponatraemia, SIADH, insomnia, anxiety, confusion, extrapyramidal symptoms, acute dystonia, tardive dyskinesia, Neuroleptic Malignant Syndrome, restless legs syndrome, blurred vision, bradycardia, QT interval prolongation, hypotension, venous thromboembolism, aspiration pneumonia, constipation, hepatocellular injury, angioedema, rhabdomyolysis, urinary retention, weight gain and elevations of hepatic enzymes.

**MARKETED BY:**



Torrent Pharmaceuticals Limited.

**IN/ AMAZEO OD Tablets 100, 200 and 400 mg/ May 2025 /02/ABPI**

(Additional information is available on request)