For the use only of a Registered Medical Practitioner (Psychiatrist) or a Hospital or a Laboratory

Abridged Prescribing Information

Amisulpride tablets I.P.

SOLIAN®

THERAPEUTIC CATEGORY

Anti-psychotic

COMPOSITION

Solian® 50 /100 /200 /400

Each uncoated tablet contains Amisulpride IP. 50mg / 100mg / 200mg

Each film coated tablet contains Amisulpride IP 400mg.

THERAPEUTIC INDICATIONS

Treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, and thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.

DOSAGE AND ADMINISTRATION

For acute psychotic episodes, oral doses between 400 and 800 mg/d are recommended. Doses above 1200 mg/d 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 characterised by predominant negative symptoms, oral doses between 50 mg/d and 300 mg/d are recommended. Doses should be adjusted individually. Solian® can be administered once daily at oral doses up to 300 mg, higher doses should be administered bid. The Minimum effective dose should be used.

Caution in elderly. Renal & Hepatic insufficiency: Dose should be reduced. Use of amisulpride from puberty to 18 years is not recommended.

SAFETY-RELATED INFORMATION

Contraindications: Hypersensitivity to amisulpride or to other ingredients of the product; concomitant prolactin-dependent tumours e.g., pituitary gland prolactinomas and breast cancer; phaeochromocytoma; children up to puberty; lactation; combinations with drugs which could induce torsades de pointes and levodopa.

Warnings: Neuroleptic Malignant Syndrome may occur. Rhabdomyolysis has also been observed in patients without Neuroleptic Malignant Syndrome If hyperthermia occurs amisulpride should be discontinued. Parkinson's disease may be worsened. Amisulpride induces a dose-dependent prolongation of the QT interval with risk of serious ventricular arrhythmias such as torsades de pointes. Before any administration, it is recommended to monitor factors which could favour the occurrence of this rhythm disorder. Concomitant antipsychotics should be avoided. Cautious if stroke risk factors and thromboembolism risk factors. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Breast cancer -Amisulpride may increase prolactin levels. Therefore, caution should be exercised and patients with a history or a family history of breast cancer should be closely monitored during amisulpride therapy. Cases of benign pituitary tumors such as prolactinoma have been observed.

Precautions: Hyperglycemia has been reported hence appropriate glycemic monitoring for patients with diabetes mellitus or with risk factors for diabetes. The seizure threshold can be lowered. Dose reduction in renal insufficiency. Caution in the elderly as possible risk of hypotension or sedation. Withdrawal symptoms have been described after abrupt cessation of high therapeutic doses of antipsychotic drugs. Thus, gradual withdrawal of amisulpride is advisable. Leukopenia, neutropenia and agranulocytosis have been reported. Unexplained infections or fever may be evidence of blood dyscrasia and requires immediate haematological investigation. Even when used as recommended, amisulpride may cause somnolence and blurred vision so that the ability to drive vehicles or operate machinery can be impaired

Pregnancy and Lactation:

The use of amisulpride is not recommended during pregnancy and in women of child-bearing potential not using effective contraception, unless the benefits justify the potential risks.

Breast feeding is contraindicated.

Adverse Reactions: Very common (≥10%): extrapyramidal symptoms. Common (≥1% and <10%): acute dystonia somnolence, insomnia, anxiety, agitation, orgasmic dysfunction, constipation, nausea, vomiting, dry mouth, hypotension, weight gain, blurred vision, increase in plasma prolactin levels may result in galactorrhoea, amenorrhoea, gynaecomastia, breast pain, and erectile dysfunction.

For full prescribing information please contact: Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072, Mumbai

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