Abridged Prescribing Information:

Active Ingredient: SOLTUS Tablet contains Amisulpride,---- 50 mg / 100 mg / 200 mg / 300 mg / 400 mg

SOLTUS OD contains Amisulpride Sustained-Release 100mg /200mg /300mg

Indication: Amisulpride is indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms. **Dosage & Administration**: **Soltus**: **s** should be administered in two equally divided portions (i.e., BID) for doses above 400 mg. 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. Doses above 800 mg/day have not been shown to be superior to lower doses and may increase the incidence of adverse events. No specific titration is required when initiating the treatment with amisulpride. Doses should be adjusted according to individual response. Doses should preferably be administered before meals. **Soltus OD :** tablets are taken orally once a day preferably before a meal. Tablets must be swallowed whole with the aid of water and without chewing, splitting, crushing or dissolving them. 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. Doses above 800 mg/day have not been shown to be superior to lower doses and may increase the incidence of adverse events. No specific titration is required when initiating the treatment with amisulpride. **Contraindication:** Known 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. **Warnings & Precautions:** Neuroleptic malignant syndrome characterised by hyperthermia, muscle rigidity, autonomic instability, and elevated CPK, may occur. In the event of hyperthermia, particularly with high daily doses, all antipsychotic drugs including amisulpride should be discontinued. Amisulpride is eliminated by the renal route. In cases of severe renal insufficiency, the dose should be decreased and intermittent treatment should be considered. There are limited data on the potential for renally-cleared drugs to interfere with the clearance of amisulpride. Therefore, amisulpride should be used with caution with other renally-excreted drugs, including lithium. The impact of hepatic impairment on hepatic metabolism and hepato-biliary excretion of amisulpride has not been studied. Amisulpride should be used with caution in patients with moderate or severe hepatic impairment. **Extrapyramidal symptoms may occur:** tremor, rigidity, hypokinesia, hypersalivation, akathisia. These symptoms are generally mild at optimal dosages and partially reversible without discontinuation of amisulpride upon administration of antiparkinsonian medication. The incidence of extrapyramidal symptoms which is dose related, remains very low in the treatment of patients with predominantly negative symptoms with doses of 50-300 mg/day. **Tardive dyskinesia** characterised by rhythmic, involuntary movements primarily of the tongue and/or face have been reported, usually after long-term administration. Antiparkinsonian medication is ineffective or may induce aggravation of the symptoms. **Pregnancy:** The safety of amisulpride during human pregnancy has not been established, and therefore use of this drug is not recommended during pregnancy unless the benefits justify the potential risks. **Specific Population: Elderly:** Amisulpride should be used with particular caution because of a possible risk of hypotension or sedation. **Renal insufficiency:** Amisulpride is eliminated by the renal route. In renal insufficiency, the dose should be reduced to half in patients with creatinine clearance (CLCR) between 30-60 mL/min and to a third in patients with CLCR between 10-30 mL/min. As there is no experience in patients with severe renal impairment (CLCR < 10 mL/min) particular care is recommended in these patients. **Adverse Reactions:** Insomnia, anxiety, agitation are common side effects (occurring in 5-10% of treated patients). Somnolence, constipation, nausea, vomiting and dry mouth may occur in up to 2% of patients. Other side effects include weight gain, acute dystonia, extrapyramidal side effects, tardive dyskinesia, hypotension, bradycardia and QTc prolongation. Amisulpride can cause hyperprolactinaemia and thus may lead to galactorrhea, gynecomastia, breast pain and amenorrhea. **Overdose:** Experience with amisulpride in overdosage is limited. Exaggeration of the known pharmacological effects of the drug has been reported. These include drowsiness and sedation, coma, hypotension and extrapyramidal symptoms. In cases of acute overdose, the possibility of multiple drug intake should be considered. Since amisulpride is weakly dialysed, hemodialysis should not be used to eliminate the drug. There is no specific antidote to amisulpride. Appropriate supportive measure should therefore be instituted: close supervision of vital functions and, because of the risk of prolongation of QT interval, continuous cardiac monitoring until the patient recovers. If severe extrapyramidal symptoms occur, anticholinergic agents should be administered.

(For details, please refer full prescribing information)

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