Summary of prescribing information for ZOLAX SR tablets

Active Ingredient: Each sustained-release tablet of ZOLAX SR contains: Alprazolam 0.5, 1, 1.5mg. **Indication:** Short-term treatment of anxiety disorder, anxiety associated with depression and panic disorders. **Dosage:** Tablets may be administered once daily, preferably in the morning. The tablets should be taken intact; they should not be chewed, crushed, or broken. Suggested total daily dose range: 3 to 6 mg/day. Dosage should be individualized for maximum beneficial effect. While the suggested total daily dosages given will meet the needs of most patients, there will be some patients who require doses greater than 6 mg/day. Initiated with a dose of 0.5 mg to 1 mg once daily. Depending on the response, the dose may be increased at intervals of 3 to 4 days in increments of no more than 1 mg/day. Slower titration to the dose levels may be advisable. In panic disorder, doses in the range of 1 to 10 mg/day. Because of the danger of withdrawal, abrupt discontinuation of treatment should be avoided. In all patients, dosage should be reduced gradually when discontinuing therapy. **Contraindications:** Hypersensitivity to alprazolam, other benzodiazepines or any ingredient; concomitantly with cytochrome P450 3A inhibitors such as ketoconazole and itraconazole. **Warning and precautions:** Concomitant use with opioids: profound sedation, respiratory depression, coma, and death. Dependence and Withdrawal Reactions, Including Seizures. Status Epilepticus: withdrawal or discontinuation. Interdose Symptoms: Early morning anxiety and emergence of anxiety symptoms between doses. Risk of Dose Reduction: Withdrawal reactions may occur. CNS Depression and Impaired Performance: cautioned against engaging in hazardous occupations or activities requiring complete mental alertness. Precautions for suicide, mania, uricosuric effect, and ataxia or oversedation. **Pregnancy & Lactation:** Benzodiazepines can potentially cause fetal harm when administered to pregnant women. Benzodiazepines are known to be excreted in human milk. Chronic administration of diazepam to nursing mothers has been reported to cause their infants to become lethargic and to lose weight. As a general rule, nursing should not be undertaken by mothers who must use alprazolam. **Interaction:** Use with Other CNS Depressants (e.g. psychotropic medications, anticonvulsants, antihistaminics, ethanol): may potentiate the action of benzodiazepine. Fluoxetine, Propoxyphene, and Oral Contraceptives: Coadministration with alprazolam increased the maximum plasma concentration of alprazolam. Cytochrome P450 3A inducers (carbamazepine): can decrease plasma levels of alprazolam. **Adverse reactions:** frequent palpitations, vertigo, blurred vision, diarrhea, vomiting, dyspepsia, abdominal pain, sedation, somnolence, memory impairment, dysarthria, coordination abnormal, ataxia, libido decreased, malaise, weakness, chest pains, back pain, muscle cramps, muscle twitching, headache, dizziness, tremor, irritability, insomnia, nervousness, derealization, restlessness, agitation, depersonalization, nightmare, difficulty in micturition, nasal congestion, hyperventilation, sweating increased. **Overdose:** Symptoms: somnolence, confusion, impaired coordination, diminished reflexes, and coma. Death has been reported. Management: respiration, pulse rate, and blood pressure should be monitored. General supportive measures should be employed, along with immediate gastric lavage. If hypotension occurs, it may be combated by the use of vasopressors. Dialysis is of limited value. Flumazenil, a specific benzodiazepine receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzodiazepine is known or suspected. The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com