Abridged Prescribing Information:

Active Ingredient: SPENZO Tab. contains Flupentixol Hydrochloride 0.5 mg

Indication: SPENZO tab. is indicated for the maintenance treatment of chronic schizophrenia and other related chronic psychoses in patients whose main manifestations do not include excitement, agitation or hyperactivity. It is also given in patients intolerant of and/or refractory to other depot preparations. It is intended for maintenance therapy only and not for short-term use (less than 3 months).

Dosage & Administration: Adults SPENZO 0.5 (flupentixol hydrochloride 0.5 mg) tablets are given by mouth. **Schizophrenia**: The dosage should be individualized and adjusted according to the severity of symptoms and tolerance to the drug. The initial recommended dose is two SPENZO 0.5 tablets (i.e., the equivalent of 1 mg flupentixol) given 3 times daily in adults. This may be increased, if necessary by 1 mg every 2 to 3 days until there is effective control of psychotic symptoms. The maximum recommended daily dose is 18 mg (in 2-3 divided portions). The usual maintenance dosage is 3 to 6 mg daily in divided doses, although doses of up to 12 mg daily or more have been used in some patients. The initial dose in elderly and debilitated patients may need to be reduced to a quarter or a half of the usual starting dose. During the initial therapeutic period, disturbance of sleep may occur, especially in those patients who have previously received neuroleptics possessing a marked sedative effect. In this event, the evening dose may be reduced. Following stabilization on SPENZO tablets, patients may be treated with SPENZO INJ. administered by the intramuscular route. Until further clinical evidence is available, SPENZO is not recommended for use in children. **Warnings & Precautions: Neuroleptic malignant syndrome -** The neuroleptic malignant syndrome (NMS) is a rare but potentially fatal complication of the use of neuroleptic drugs. Core features of NMS are hyperthermia, muscular rigidity and fluctuating consciousness along with autonomic dysfunction (labile blood pressure, tachycardia, diaphoresis). Aside from immediate cessation of the neuroleptic medication the use of general supportive measures and symptomatic treatment are vital. Note that neuroleptic malignant syndrome has been reported with flupentixol. Flupentixol should be used with caution in liver damage, cerebrovascular or renal insufficiency, and severe cardiovascular disorders. The drug should be used with caution in patients with Parkinsonism. Although its anticholinergic properties are weak, flupentixol should be used with caution in patients who are known or are suspected to have glaucoma, and in those patients who might be exposed to extreme heat, or organophosphorus insecticides or who are receiving atropine or related drugs. **Pregnancy:** Safety in pregnancy has not been established. Therefore it should not be administered to women of childbearing potential unless, in the opinion of the physician, the expected benefit to the patient outweighs the potential risk to the foetus. **Adverse Reactions:** The most common adverse reactions reported with flupentixol have been extrapyramidal symptoms. Flupentixol shares many of the pharmacological properties of other thioxanthenes and phenothiazines. Therefore, the known adverse reactions of these drugs should be borne in mind when flupentixol is used. Extrapyramidal symptoms, including hypo- and hyperkinetic states, tremors, pseudoparkinsonism, dystonia, hypertonia, akathisia, oculogyric crises and tardive dyskinesia. The symptoms, if they are to occur, usually appear within the first few days after administration and can usually be controlled or totally curtailed by reduction in dosage and/or standard antiparkinsonian medication. **Overdose:** In general, the main therapy for all overdoses is supportive and symptomatic care. Overdosage may cause somnolence, coma, extreme agitation, excitement, confusion, convulsions, extrapyramidal symptoms, shock, respiratory and circulatory collapse and hyper- or hypothermia. Treatment is symptomatic and supportive. No further injections of flupenthixol should be given. Measures to support the respiratory and cardiovascular systems should be instituted. If severe hypotension occurs, an intravenous vasopressor drug should be administered immediately. Epinephrine (adrenaline) should not be used as further lowering of blood pressure may result. Convulsions may be treated with diazepam and extrapyramidal symptoms with an antiparkinsonian medication.

(For details, please refer full prescribing information)

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productqueries@intaspharma.com