Abridged Prescribing Information:

Active Ingredient: INJECTION SPENZO DEPOT 20/ 40 contains Flupentixol Decanoate 20 mg/1ml, Flupentixol Decanoate 40 mg/2ml

Indication: SPENZO INJ. 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**: Patients not previously treated with long-acting depot neuroleptics should be given an initial test dose of 5 mg to 20 mg of INJECTION SPENZO DEPOT. An initial dose of 20 mg is usually well tolerated; however, a 5 mg test dose of INJECTION SPENZO DEPOT is recommended in elderly, frail and cachectic patients, and in patients whose individual or family history suggests a predisposition to extrapyramidal reactions. In the subsequent 5 to 10 days, the therapeutic response and the appearance of extrapyramidal symptoms should be carefully monitored. Oral neuroleptic drugs may be continued, but in diminishing dosage, during this period. In patients previously treated with long-acting depot neuroleptics who displayed good tolerance to these drugs, an initial dose of 20 to 40 mg may be adequate. Patients transferred from fluphenazine decanoate should receive of INJECTION SPENZO DEPOT in a dose ratio of 25 mg fluphenazine decanoate equals 40 mg flupentixol decanoate. For haloperidol decanoate, dose equivalence has not been systematically established, but is approximately 40 mg flupentixol decanoate equals 50 mg haloperidol decanoate. Subsequent doses and the frequency of administration must be determined for each patient. There is no reliable dosage comparability between a shorter-acting neuroleptic and depot flupentixol, and therefore, the dosage of the long-acting drug must be individualised. Except in particularly sensitive patients, a second dose of 20 mg or 40 mg of INJECTION SPENZO DEPOT can be given 4 to 10 days after the initial injection. Subsequent dosage adjustments are made in accordance with the response of the patient, but the majority of patients can be adequately controlled by 20 to 40 mg of flupentixol decanoate every 2 to 4 weeks. The optimal amount of the drug has been found to vary with the clinical circumstances and individual response. **Contraindication:** SPENZO INJ. is contraindicated in patients with known hypersensitivity to flupentixol, other thioxanthenes, or to the excipient used (coconut oil - fractionated) in the injection. The possibility of cross-sensitivity between the thioxanthenes and phenothiazine derivatives should be considered. Flupentixol is also contraindicated in the presence of CNS depression due to any cause (e.g. intoxication with alcohol, barbiturates or opiates), circulatory collapse, comatose states, suspected or established subcortical brain damage, blood dyscrasias and pheochromocytoma. SPENZO INJ. 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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