Deanipyx™

Flupentixol 0.5 mg & Melitracen 10 mg Tablets

Composition :
Each film coated tablet contains:
Flupentixol Hydrochloride BP
eq. to Flupentixol ……..……. 0.5 mg
Melitracen Hydrochloride
eq. to Melitracen ……..……..…. 10 mg
Excipients……..……..…. Q.S.
Color: Lake of Erythrosine, Titanium Dioxide BP

PHARMACODYNAMICS:

- Flupentixol:-
Pharmacotherapeutic group: Neuroleptics (antipsychotics)
ATC code: N05AF01

- Melitracen:-
Pharmacotherapeutic group: Tricyclic antidepressant (TCA)
ATC code: N06AA14

Mechanism of Action of Flupentixol and Melitracen tablets:
Flupentixol is a typical antipsychotic. It works by blocking the action of dopamine, a chemical messenger in the brain that affects thoughts and mood. Melitracen is a tricyclic antidepressant which increases the levels of chemical messengers in the brain that help in regulating the mood and treat depression.

PHARMACOKINETICS:
Mean oral bioavailability is about 55%. Maximum drug serum concentrations occur about 4 hours after dosing and the biological half-life is about 35 hours.Flupentixol is widely distributed in the body. Metabolism is by sulphoxidation, N-dealkylation and glucuronic acid conjugation. Excretion is via the urine and faeces.

INDICATIONS
Depression.

RECOMMENDED DOSE
Depression:-
Adult:- Per tablet contains flupentixol 0.5 mg and melitracen 10 mg: 1 tablet in the morning and at midday. May double morning dose in severe cases. Not to exceed 4 tablets daily.
Elderly:- Per tablet contains flupentixol 0.5 mg and melitracen 10 mg: 1 tablet in the morning. For severe cases: 1 tablet in the morning and at midday.

METHOD OF ADMINISTRATION:
For oral use.

CONTRAINDICATIONS:
Circulatory collapse, depressed level of consciousness due to any cause, coma. Severe depressing requiring hospitalisation or electroconvulsive therapy. Not recommended for use in states of excitement or overactivity.

WARNING AND PRECAUTIONS
Unsafe in porphyria. Caution when used in patients with epilepsy; Parkinson's disease; narrow angle glaucoma; prostatic hypertrophy; hypothyroidism; hyper-thyroidism; liver disease; cardiac disease or arrhythmias; severe respiratory disease; renal failure; myasthenia gravis; phaeochromocytoma. Patients withhypersensitivity to thioxanthenes or other antipsychotics. Close monitoring for changes in behaviour, suicidal thoughts or clinical worsening during the initial part of the treatment is recommended. May impair control of diabetes; monitor blood glucose in diabetics. Withdrawal should be gradual.

INTERACTIONS WITH OTHER MEDICAMENTS
Increased risk of adverse effects when used with alcohol. May potentiate the effects of general anaesthetics and anticoagulants, and prolong the action of neuromuscular blockers. May increase anticholinergic effects of atropine and drugs with anticholinergic activity. May increase risk of neurotoxicity when used with sibutramine or lithium. Avoid concurrent usage with drugs that cause QT prolongation or cardiac arrhythmias. May inhibit metabolism of TCAs. May antagonise effects of adrenaline and sympathomimetics, and reverse anti-hypertensive effects of guanethidine.

PREGNANCY AND LACTATION
Flupentixol-melitracen combination should preferably not be given during pregnancy and lactation.

UNDESIRABLE EFFECTS
Constipation, Urinary retention, Weight gain, Sleepiness, Orthostatic hypotension (sudden lowering of blood pressure on standing), Increased heart rate, Increased prolactin level in blood, Blurred vision, Dryness in mouth, Muscle stiffness, Tremor, Restlessness.

OVERDOSE AND TREATMENT
Overdosage may cause somnolence, or even coma, extrapyramidal symptoms, convulsions, hypotension, shock, hyper-or hypothermia. ECG changes, QT prolongation, Torsade de Pointes, cardiac arrest and ventricular arrhythmias have been reported when administered in overdose together with drugs known to affect the heart.Treatment is symptomatic and supportive, with measures aimed at supporting the respiratory and cardiovascular systems. The following specific measures may be employed if required
- anticholinergic antiparkinson drugs if extrapyramidal symptoms occur.
- sedation (with benzodiazepines) in the unlikely event of agitation or excitement or convulsions.
- noradrenaline in saline intravenous drip if the patient is in shock. Adrenaline must not be given.
- gastric lavage should be considered.

STORAGE CONDITION : Store below 30°C.
Protect from light & moisture.
Keep out of reach of children.

DOSAGE FORM AND PACKAGING AVAILABLE
DOSAGE FORM: Tablets
PACKAGING: 10 x 10 Alu-Pvc Blister

Marketed by:
PYXUS
PYXUS PHARMACEUTICALS PVT. LTD.
A/707, Mondeal Heights, Beside Novotel Hotel,
Nr. Iscon Square, S.G. Highway, Ahmedabad,
Gujarat- 380015 (India).