For Medical/Pharmacy Professionals Only"

Flupentixol Injection IP 20 mg/ml

AMERICAN
HYPEXOL DEPOT 40
Injection

Composition:
Each ml contains:

Flupentixol Decanoate	IP	20 mg
Oily base		q.s.

PHARMACEUTICAL FORM:
Solution for Injection

DESCRIPTION OF ACTIVE INGREDIENTS:
Flupentixol is a neuroleptic of the thioxanthene group. It exists in two geometric isomers, the cis(Z) and trans(E) forms of which only the cis(Z)-flupenthixol is pharmacologically active. Flupenthixol decanoate is produced by esterification of cis(Z)-flupentixol with decanoic acid.

PHARMACOLOGICAL PROPERTIES:
Pharmacotherapeutic group: Neuroleptics (antipsychotics)

Flupentixol is a non-sedating antipsychotic drug of the thioxanthene group. Its primary pharmacological action is dopamine blockade. Flupentixol has a high affinity for D1 and D2 receptors. Flupentixol Injection contains the deconoic ester of flupentixol in thin vegetable oil.

PHARMACOKINETICS
After intramuscular injection, the ester is slowly released from the oil depot and is rapidly hydrolysed to release flupentixol. Flupentixol is widely distributed in the body and extensively metabolized in the liver. Peak circulating levels occur around 7 days after administration.

THERAPEUTIC INDICATION:
The treatment of schizophrenia and other psychoses.
Use of Flupentixol Injection should be restricted to those stabilised on oral therapy.

DOSAGE AND ADMINISTRATION
Adults The usual dosage of flupentixol decanoate lies between 50 mg every 4 weeks and 300 mg every 2 weeks, but some patients may require up to 400 mg weekly. The maximum single dose at any one time is 400 mg. For example, 800 mg ever 2 weeks should not be given. Other patients may be adequately maintained on dosages of 20- 40 mg flupentixol decanoate every 2-4 weeks. In patients who have not previously received depot antipsychotic, treatment is usually started with a small dose (e.g. 20. mg) to assess tolerability. An interval of at least one week should be allowed before the second injection is given at a dose consistent with the patients' condition.

Older patients In accordance with standard medical practice, initial dosage may need to be reduced to a quarter or half the normal starting dose in the frail or older patients.
Children Flupentixol is not recommended for use in children due to lack of clinical experience.
Patients with reduced renal function Flupentixol has not been studied in renal impairment. Increased cerebral sensitivity to antipsychotics has been noted in severe renal impairment.
Patients with reduced hepatic function Flupentixol has not been studied in hepatic impairment. It is extensively metabolised by the liver and particular caution should be used in this situation and serum level monitoring is advised. Flupentixol should be initiated at low doses orally to check for tolerability before switching to the depot formulation**.**

Method of administration
Deep intramuscular injection into the upper outer buttock or lateral thigh.

CONTRAINDICATION:
Hypersensitivity to the active substance or to any of the excipients.
Circulatory collapse, depressed level of consciousness due to any cause (e.g. intoxication with alcohol, barbiturates or opiates), coma.
Not recommended for excitable or agitated patients.

SPECIAL WARNING AND PRECAUTIONS FOR USE:
Caution should be exercised in patients having: liver disease; cardiac disease or arrhythmias; severe respiratory disease; renal failure; epilepsy (and conditions predisposing to epilepsy e.g. alcohol withdrawal or brain damage); Parkinson's disease; narrow angle glaucoma; prostatic hypertrophy; hypothyroidism; hyperthyroidism; myasthenia gravis; phaeochromocytoma and patients who have shown hypersensitivity to thioxanthenes or other antipsychotics.
Treatment: Discontinuation of the neuroleptic. Symptomatic treatment and use of general supportive measures. Dantrolene and bromocriptine may be helpful.
Symptoms may persist for more than a week after oral neuroleptics are discontinued and somewhat longer when associated with the depot forms of the drugs.
Blood dyscrasias, including thrombocytopenia, have been reported rarely. Blood counts should be carried out if a patient develops signs of persistent infection.
As described for other psychotropics flupentixol may modify insulin and glucose responses calling for adjustment of the antidiabetic therapy in diabetic patients

DRUG INTERACTIONS:
Antipsychotics may enhance the cardiac depressant effects of quinidine; the absorption of corticosteroids and digoxin. The hypotensive effect of vasodilator antihypertensive agents such as hydralazine and α-blockers (e.g. doxazosin), or methyl-dopa may be enhanced.
Increases in the QT interval related to antipsychotic treatment may be exacerbated by the co-administration of other drugs known to significantly increase the QT interval.
Co-administration of such drugs should be avoided. Relevant classes include:
class Ia and III antiarrhythmics (e.g. quinidine, amiodarone, sotalol, dofetilide)
some antipsychotics (e.g. thioridazine)
some macrolides (e.g. erythromycin)
some antihistamines
some quinolone antibiotics (e.g. moxifloxacin)
The above list is not exhaustive and other individual drugs known to significantly increase QT interval (e.g. cisapride, lithium) should be avoided.
Drugs known to cause electrolyte disturbances such as thiazide diuretics (hypokalaemia) and drugs known to increase the plasma concentration of flupentixol should also be used with caution as they may increase the risk of QT prolongation and malignant arrhythmias.
Antipsychotics may antagonise the effects of adrenaline and other sympathomimetic agents, and reverse the antihypertensive effects of guanethidine and similar adrenergic-blocking agents. Antipsychotics may also impair the effect of levodopa, adrenergic drugs and anticonvulsants.
The metabolism of tricyclic antidepressants may be inhibited and the control of diabetes may be impaired.

PREGNANCY AND LACTATION
Pregnancy: As the safety of this drug during pregnancy has not been established, use during pregnancy, especially the first and last trimesters, should be avoided, unless the expected benefit to the patient outweighs the potential risk to the foetus.
Neonates exposed to antipsychotics (including Flupentixol) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder.
Consequently, newborns should be monitored carefully.
Animal studies have shown reproductive toxicity.
Breast-feeding: Flupentixol is excreted into the breast milk. If the use of Flupentixol is considered essential, nursing mothers should be advised to stop breast-feeding.
Fertility: In humans, adverse events such as hyperprolactinaemia, galactorrhoea, amenorrhoea, libido decreased, erectile dysfunction and ejaculation failure have been reported. These events may have a negative impact on female and/or male sexual function and fertility.
If clinical significant hyperprolactinaemia, galactorrhoea, amenorrhoea or sexual dysfunctions occur, a dose reduction (if possible) or discontinuation should be considered. The effects are reversible on discontinuation.

SIDE EFFECTS:
The following common side effects may occur:
Immune system disorders, endocrine disorder, metabolism and nutrition disorders, psychiatric disorders, psychiatric disorders, nervous system, eye disorders, cardiac disorders, vascular disorders, respiratory, thoracic and mediastinal disorders, gastrointestinal disorders, hepatobiliary disorders, skin and subcutaneous tissue disorders, musculoskeletal and connective tissue disorder, renal and urinary disorders, pregnancy, puerperium and perinatal conditions, reproductive system and breast disorders, general disorders and administration site conditions.

OVERDOSAGE
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.

STORAGE CONDITION:
Storage : Store protected from light at a temperature not exceeding 30°C.
Do not allow to freeze.

PRESENTATION
1ml clear glass ampoule packed in a 10×1 ml Tray pack along with package insert in a monocarton.

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