FLUPHENAZINE DECANOATE

FLUPDEC

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25 mg/mL
Solution for Injection (I.M.)
ANTIPSYCHOTIC

FORMULATION:
Each ampoule contains:
Fluphenazine Decanoate, BP……25 mg

PRODUCT DESCRIPTION:
Type I amber glass ampoule contains yellow coloured solution free from visible particle and fibers.

PHARMACODYNAMICS:
Fluphenazine decanoate is an ester of the potent neuroleptic fluphenazine, a phenothiazine derivative of the piperazine type. The ester is slowly absorbed from the intramuscular site of injection and is then hydrolysed in the plasma to the active therapeutic agent, fluphenazine. Extrapyramidal reactions are not uncommon, but fluphenazine does not have marked sedative or hypotensive properties.

PHARMACOKINETIC:
Fluphenazine decanoate undergoes slow absortion from the site of intramuscular injection and is hydrolyzed to release fluphenazine.
Fluphenazine is extensively metabolised in the liver and excreted in the urine and faeces as unchanged drug and metabolites.
Plasma level profiles of fluphenazine decanoate injection have shown half-lives of plasma clearance ranging from 2.5 to 16 weeks; this emphasizes the importance of adjusting the dose and dose interval to the individual requirements of each patient. Because of the slow decline of plasma levels in most patients, a reasonably stable plasma level can usually be achieved with injections spaced at 2 to 4 weeks intervals.

INDICATIONS:
For the treatment of a variety of psychiatric disorders including schizophrenia, mania, severe anxiety, and behavioral disturbances.

DOSAGE AND ADMINISTRATION:
Initial: Usual Adult dose: 12.5 to 25 mg (0.5 – 1 mL) every 2 to 5 weeks intramuscularly. The optimal amount of the drug and frequency of administration must be determined for each patient, since dosage requirement have been found to vary with clinical circumstances as well as with individual response to the drug. Or as prescribed by the physician.

CONTRAINDICATIONS:
Phenothiazines are contraindicated in patients with suspected or established subcortical brain damage. Phenothiazine compounds should not be used in patients receiving large doses of hypnotics. Fluphenazine decanoate is not intended for use in children under 12 years of age. Fluphenazine decanoate injection is contraindicated in patients who have hypersensitivity to Fluphenazine, cross-sensitivity to Phenothiazine derivatives may occur.

PRECAUTIONS:
Extrapyramidal syndromes are particularly likely to occur. Dystonic reactions and akathisia are common and may not be recognized when they do not resemble classical parkinsonism. Dyskinesias may become irreversible. Occasionally galactorrhea, augmentation of epilepsy, epigastric pain or jaundice may occur.
Fluphenazine may release stored catecholamines and therefore a risk in cases of phaeochromocytoma.
1. Pregnancy
2. Respiratory depression
3. Geriatric patients

WARNINGS AND PRECAUTIONS:
Particular care is required when using fluphenazine in any of the following conditions:
-Liver disease; cardiac disease or the presence of cardiac arrhythmias; thyrotoxicosis; severe respiratory disease; epilepsy or conditions predisposing to epilepsy, such as alcohol withdrawal or brain damage; Parkinson's disease; patients with history of hypersensitivity to other phenothiazines; personal or family history of narrow angle glaucoma; very hot weather or where the ambient temperature is high; the elderly, especially if frail or at risk of hypothermia; hypothyroidism; myasthenia gravis; prostatic hyperthrophy.
**If only part used, discard the remaining solution.
-Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Fluphenazine and preventive measures under taken.
Increased Mortality in Elderly people with Dementia.
-Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those whose are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increase risk is not known.
Fluphenazine is not licensed for the treatment of dementia-related behavioral disturbances.

PREGNANCY AND LACTATION:
Use in pregnancy: The safety for the use of this drug during pregnancy has not been established; therefore, the possible hazards should be weighed against the potential benefits when administering this drug to pregnant patients.
Neonates exposed to antipsychotics (including Fluphenazine) during the third trimester of pregnancy are at risk of adverse reactions including extra pyramidal 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.

Nursing mothers: Breast feeding is not recommended during treatment with depot fluphenazines, owing to the possibility that fluphenazine may be excreted in the breast milk.

ADVERSE EFFECTS
The side effects most frequently reported with Phenothiazine compounds are extrapyramidal symptoms including pseudoparkinsonism, dystonia, dyskinesia, akathisia, oculogyric crises, opisthotonos, and hyperreflexia. Muscle rigidity sometimes accompanied by hyperthermia has been reported following use of Fluphenazine decanoate. Most often these extrapyramidal symptoms are reversible; one can expect a higher incidence with Fluphenazine decanoate than with less potent piperazine derivatives or with straight chain Phenothiazines such as Chlorpromazine. With any given phenothiazine derivative, the incidence and severity of such reactions depend more on individual patients sensitivity than on the other factors, but dosage level and patient age are also determinants. Extra pyramidal reactions may be alarming and the patient should be usually be controlled by administration of anti-parkinsonian drugs, such as benztropine mesylate or intravenous caffeine and sodium benzoate injection and by subsequent reduction in dosage. Liver damage as manifested by cholestatic jaundice may be encountered, particularly during the first months of therapy; treatment should be discontinued if this occurs. An increase in cephalin flocculation sometimes accompanied by alterations in other liver function tests, has been reported in patients receiving the enanthate ester of Fluphenazine (a closely related compound). Although this is not a general feature of Fluphenazine, potentiation of central nervous depressants (opiates, analgesics, antihistamines, barbiturates, alcohol) may occur. The following adverse reactions have also occurred with phenothiazine derivatives; systemic lupus erythematosus-like syndrome, hypotension severe enough to cause fatal cardiac arrest, altered electrographic and electroencephalogic tracings, altered cerebrospinal fluid proteins, cerebral edema, asthma, laryngeal edema, angioneurotic edema; with long-term use skin pigmentation and lenticular and corneal opacities. Injections of Fluphenazine are extremely well tolerated, local tissue reactions occurring only rarely, angioneurotic edema; with long-term use skin pigmentation and lenticular and corneal opacities. Injections of Fluphenazine are extremely well tolerated, local tissue reactions occurring only rarely.

DRUG INTERACTION:
The possibility should be borne in mind that phenothiazines may:
-Increase the CNS-depressant effects of drugs such as alcohol, general anesthetics, hypnotics, sedatives, or strong analgesics
-Antagonize the action of sympathomimetic agents, including adrenaline and reverse the blood-pressure lowering effects of adrenergic-blocking agents such as guanethidine and clonidine.
-Impair the anti-parkinsonian effect of L-dopa, the effect of anticonvulsants, the metabolism of tricyclic antidepressants and the control of diabetes mellitus
-Increase the effects of anticoagulants and antidepressants
-Interaction with lithium
-Enhance the anticholinergic effects of other anticholinergic drugs, including antimuscarinic and antiparkinsonian agents. Phenothiazines may also enhance the cardiac depressant effects of quinidine, the absorption or corticosteroids and digoxin and of neuromuscular blocking agents.

OVERDOSE AND TREATMENT:
Overdosage should be treated symptomatically and supportively, extrapyramidal reactions will respond to oral or parenteral anti-parkinsonian drugs such as procyclidine or benzatropine. In cases of severe hypotension, all procedures for the management of circulatory shock should be instituted, eg. vasoconstrictors and/or intravenous fluids. However, only the vasoconstrictors metaraminol or noradrenaline should be used, as adrenaline may further lower the blood pressure through interaction with the phenothiazine.

STORAGE CONDITION:
Store at temperatures not exceeding 30ºC. Protect from light.

AVAILABILITY:
Type I Amber Glass Ampoule x 1 mL (Box of 5's)

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Patient seek medical attention immediately at the first sign of any adverse drug reaction.

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