

FLUPHENAZINE HCl **5 mg tablets**

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about FLUPHENAZINE HCl

Each tablet contains 5 mg fluphenazine HCl. FLUPHENAZINE HCl tablets are for oral use. Fluphenazine is a piperazine phenothiazine antipsychotic agent used in the management of psychotic disorders (schizophrenia, delusions and hallucinations).

Fluphenazine acts by altering the effects of dopamine in the central nervous system. In addition, it exerts anticholinergic and alpha-adrenergic blocking effects.

Fluphenazine is used in the treatment of a variety of psychiatric disorders including schizophrenia, mania, delirium, severe anxiety, and behavioral disturbances.

The way to take FLUPHENAZINE HCl

Take FLUPHENAZINE HCl as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage and duration of treatment are individualized and adjusted according to the severity of the condition under treatment and the response obtained. Treatment is instituted with a low initial dose which may be increased, if necessary, until the desired clinical effect is achieved.

The usual initial dose for adults in the treatment of schizophrenia, mania, and other psychoses is half a tablet to 2 tablets per day (2.5 mg to 10 mg/day) in 2 to 3 divided doses.

Dose is then increased according to response. Therapeutic effect is often achieved with doses less than 20 mg/day. However, daily doses up to 40 mg may be necessary. Dosage may subsequently be reduced.

Fluphenazine should be given in reduced dosage to elderly patients.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in case of:

- history of hypersensitivity to any of the components, or cross sensitivity with other drugs especially other phenothiazine derivatives
- greatly depressed states due to central nervous system depressants
- bone-marrow suppression
- liver damage
- narrow angle glaucoma
- history of agranulocytosis

Precautions

- Consult your doctor before using this medication in case of pregnancy or lactation. Lactation should be avoided during treatment with this drug.

- This drug may impair mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery.

- This drug must be used with caution in elderly patients and in patients with epilepsy, history of seizures, liver or renal diseases, history of glaucoma, prostatic hypertrophy, cardiovascular disease, respiratory disorders, hypocalcemia or Parkinson's disease.

- Periodic evaluation of blood count and ophthalmologic examinations are recommended during long term treatment.

- Inform your doctor in case of rise in body temperature, sore throat or if signs of infection occur.
- Avoid prolonged exposure to sunlight and extreme heat during the treatment.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Avoid drinking alcoholic beverages during the treatment with this medication.

Use with caution with levodopa, lithium, magnesium, aluminum and calcium salts, antihypertensives, central nervous system depressants (barbiturates, narcotic analgesics, sedative antihistamines H1, benzodiazepines), anticholinergics, sultopride, amantadine, bromocriptine, lisuride, pergolide, piribedil, ropinirole, cabergoline, pramipexole, and apomorphine.

Adverse reactions

The most reported adverse reactions include: extrapyramidal reactions, tardive dyskinesia (a movement disorder), Neuroleptic Malignant Syndrome (pale skin, hyperpyrexia, muscle rigidity and altered mental status), drowsiness, restlessness, nausea, dry mouth, constipation, urinary retention, allergic reactions, dermatitis, elevation of prolactin levels, photosensitivity, ophthalmic disorders, hematological effects, seizures and postural hypotension.

Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

FLUPHENAZINE HCl 5 mg, pack of 20 tablets

Revision date: 05/2007

FLPT5/002