Fluphenazine hydrochloride tablets are indicated in the management of the symptoms of, or discomforts associated with, schizophrenia.

The 10 mg tablets are orange film-coated, triangular shaped tablets debossed with 10 on one side of the tablet and 74 on the other side. They are available as follows: NDC 51079-487-20 - Unit dose blister packages of 100 (10 tablets each).

The 5 mg tablets are green film-coated, triangular shaped tablets debossed with 5 on one side of the tablet and 8 on the other side. They are available as follows: NDC 51079-486-20 - Unit dose blister packages of 100 (10 tablets each).

The 2.5 mg tablets are yellow film-coated, triangular shaped tablets debossed with 2.5 on one side of the tablet and 5 on the other side. They are available as follows: NDC 51079-485-20 - Unit dose blister packages of 100 (10 tablets each).

The 1 mg tablets are white film-coated, triangular shaped tablets debossed with M on one side of the tablet and 4 on the other side. They are available as follows: NDC 51079-484-20 - Unit dose blister packages of 100 (10 tablets each).

Fluphenazine hydrochloride is a tris(2-chloroethyl) phenothiazine derivative intended for the management of schizophrenia. Chemically it is 4-[3-(2-trifluoromethyl) phenothiazin-10-yl]propyl]-1 square molecule as follows: 

\[
\text{C}_{22}\text{H}_{26}\text{F}_3\text{N}_3\text{OS} \cdot 2\text{HCl}
\]

HOW SUPPLIED: Fluphenazine hydrochloride tablets, USP are available containing either 1 mg, 2.5 mg, 5 mg or 10 mg of fluphenazine hydrochloride, USP.

Indications and Usage:
Fluphenazine hydrochloride is a tris(2-chloroethyl) phenothiazine derivative intended for the management of schizophrenia. Chemically, it is represented by the following structural formula:

\[
\text{C}_2\text{H}_2\text{F}_3\text{N}_3\text{OS} \cdot 2\text{HCl}
\]

Fluphenazine hydrochloride tablets, USP are available containing either 1 mg, 2.5 mg, 5 mg or 10 mg of fluphenazine hydrochloride, USP.

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Fluphenazine hydrochloride tablets, USP are available containing either 1 mg, 2.5 mg, 5 mg or 10 mg of fluphenazine hydrochloride, USP.
Pregnancy:

There is no general agreement about specific pharmacological, medical monitoring, and 3) treatment of any concomitant serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreat- ed or inadequately treated extrapyramidal signs and symptoms (e.g., dyskinesia, dystonia, dyskinesia, ataxia, oculogyric crises, opsoclonus, and hyperreflexia. Most often these extrapyramidal symptoms are reversible; however, they may be persistent (see below). With any neuroleptic drug, beneficial effects on these symptoms depend more on individual patient sensitivity than on other factors, and dosage level and patient age are also determinants.

Extrapyramidal reactions may be alarming, and the patient should be forewarned and reassured. These reactions can usually be controlled by reducing or temporarily discontinuing dosage.

Malignant Syndrome (NMS) has been reported in association with the symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS). There are a number of potential risk factors associated with this reaction, including abrupt or high-dose therapy, geriatric status, and concomitant use of a number of drugs, including other antipsychotic agents (see WARNINGS: Neuroleptic Malignant Syndrome). NMS in association with antipsychotic drugs is characterized by hyperpyrexia, muscle rigidity, altered mental status and evi- dence of autonomic dysfunction (tachycardia, diaphoresis, and cardiac dysrythmias). The diagnosis of NMS is complicated. In an adult or in a child, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS).

Other CNS Effects:

There have been reports of agitation, hypertonia, hyperreflexia, tremor, dystonia, and nystagmus. Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs (see WARNINGS: Neuroleptic Malignant Syndrome), in patients with a history of convulsions, in patients with special medical disorders, such as mithal intoxication or other car- diorespiratory depression, and in conditions where the differential diagnosis includes hyperpyrexia, muscle rigidity, altered mental status and evi- dence of autonomic dysfunction (tachycardia, diaphoresis, and cardiac dysrythmias). The diagnosis of NMS is complicated. In an adult or in a child, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS).

Abrupt withdrawal:

In general, phenothiazines do not produce withdrawal reactions with phenothiazine compounds, and should therefore be provided. However, patients with pheochromocytoma, cerebral vascular or renal damage as manifested by cholestatic jaundice, may be especially prone to hypotensive phenomena.

Hypotension has rarely presented a problem with fluphenazine. Although this is not a general feature of fluphenazine, potent- ial hypotensive phenomena and cardiovascular and hy- potensive phenomena have been reported in patients receiving fluphenazine and other phenothiazines. Previous brain damage or seizures may be predisposing factors. The use of fluphenazine in these patients should be carefully monitored. When used in elderly patients or in patients with hypertension or heart disease, the possibility of low blood pressure or syncope should be considered.

Other CNS Effects:

Although there have been occasional reports of pheno- thiazine derivatives with systemic lupus erythematosus-like syn- dromes, no cases of lupus erythematosus-like syndrome or systemic lupus erythematosus has been reported with fluphenazine hydro- chloride.

Hypotension has rarely presented a problem with fluphenazine. However, patients with pheochromocytoma, cerebral vascular or renal insufficiency, or a severe cardiac reserve deficiency such as mitral insufficiency appear to be particularly prone to hypotensive reactions with phenothiazine compounds, and should therefore be observed closely when the drug is administered. If severe hypoten- sion or postural hypotension occurs, the fluphenazine hydro- chloride tablet should not be given and the drug should be followed until recovery.

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justifications in dos age may be necessary dur ing the course of
often achieved with doses un der 20 mg daily. Patients re maining
parenteral dose of fluphenazine. Treatment is best instituted with
the oral dose has been found to be approximately 2 to 3 times the
be indicated (see package insert for conversion information).
forms, conversion to the long-acting fluphenazine decanoate may
dosage of orally ad min istered fluphenazine hydrochloride dosage
therapy to meet the patient's requirements.
be carefully determined for each individual, since optimal dosage
patients may range initially from 2.5 mg to 10 mg and should be
drastically narrowed, and current, optimal dosage levels are
often achieved with doses under 20 mg daily. Patients remaining
severely disturbed or inadequately controlled may require upward
titation of dosage. Daily doses up to 40 mg may be necessary;
controlled clinical studies have not been performed to demon-
strate safety of prolonged administration of such doses.
When symptoms are controlled, dosage can generally be re-
duced gradually to daily maintenance doses of 1 mg to 5 mg, often
given by small, divided doses. Continued treatment is need-
ed to achieve maximum therapeutic benefit; further ad-
junctive treatment may be desirable in some cases. The course of
therapy to meet the patient’s requirements.
For psychiatric patients who have been stabilized on a fixed daily
dosage of orally administered fluphenazine hydrochloride dosage
form for conversion to the long-acting fluphenazine decanoate may
be indicated (see package insert for conversion information).
For geriatric patients, the suggested starting dose is 1 mg to
2.5 mg daily, adjusted according to the response of the patient.
ALTERATIONS IN DOSAGE

ADDITIONAL INFORMATION

HOW SUPPLIED: Fluphenazine Hydrochloride Tablets, USP are available containing either 1 mg, 2.5 mg, 5 mg or 10 mg of flu-
phenazine hydrochloride, USP.
The 1 mg tablets are white film-coated, triangular shaped tablets debossed with Mn on one side of the tablet and 4 on the
other side. They are available as follows: NDC 51078-465-20 - Unit dose blister packages of 100 (10 cards of 10 tablets each).
The 2.5 mg tablets are yellow film-coated, triangular shaped tablets debossed with Mn on one side of the tablet and 8 on the
other side. They are available as follows: NDC 51078-466-20 - Unit dose blister packages of 100 (10 cards of 10 tablets each).
The 5 mg tablets are green film-coated, triangular shaped tablets debossed with Mn on one side of the tablet and 74 on the
other side. They are available as follows: NDC 51078-467-20 - Unit dose blister packages of 100 (10 cards of 10 tablets each).
The 10 mg tablets are orange film-coated, triangular shaped tablets debossed with Mn on one side of the tablet and 97 on the
other side. They are available as follows: NDC 51078-468-20 - Unit dose blister packages of 100 (10 cards of 10 tablets each).
DESCRIPTION: Fluphenazine hydrochloride is a trifluoromethyl
phenothiazine derivative intended for the management of schizo-
phrenia. Chemically it is 4-[3-[2-(Trifluoromethyl) phenothiazin-
5-yl]propyl]-1-piperazine ethanol dihydrochloride which may be
represented by the following structural formula:

\[
\text{C}_2\text{H}_5\text{F}_3\text{C} = \text{N} = \text{S} = \text{CH}_2
\]

Each tablet, for oral administration, contains 1 mg, 2.5 mg, 5 mg, or 10 mg of fluphenazine hydrochloride, USP per tablet.
Inactive ingredients are: hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized
starch, sodium lauret sulfate and titanium dioxide. The following additional product specific inactive ingredients are employed:
1 mg – calcium sulfate hydrous, hydroxypropyl cellulose and talc
2.5 mg – lactose, polydextrose, sodium algin ate and triac tin
5 mg – hydroxypropyl cellulose
10 mg – lactoh, polydextrose, sodium alginate and triacin

CLINICAL PHARMACOLOGY: Fluphenazine hydrochloride has activity at all levels of the central nervous system as well as
on multiple organ systems. The mechanism whereby its therapeutic action is exerted is unknown.
INDICATIONS AND USAGE: Fluphenazine hydrochloride tablets are indicated in the management of manifestations of psy-
hotic disorders.

Fluphenazine hydrochloride has not been shown effective in the management of behavioral complications in patients with
mental retardation.

CONTRAINDICATIONS: Phenothiazines are contraindicated in patients with suspected or established neona
tal or infantile scal ene jaundice, congenital or familial porphyria, severe hypotension, cardiogenic or infected
cardiac failure, increased intracranial pressure, active peptic ulcer
crises or liver precacie and may occur.

WARRNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with demen-
tia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Fluphenazine hydrochloride is not approved for the treatment of patients with dementia-related
psychosis (see BOXED WARNING).

Tardive Dyskinesia: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with neuroleptic (antipsychotic) drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict at the inception of neu- roleptic treatment which patients are likely to develop the syn-
drome. Whether neuroleptic drug products differ in their potential
to cause tardive dyskinesia is unknown.

Both the development of the syndrome and the likelihood that it will become irreversible are believed to increase as the
duration of treatment and the total cumulative dose of neurolep-
cic drugs administered to the patient increase. However, the syn-
drome can develop, although much less commonly, after relative-
ly brief treatment periods at low doses.

There is no known treatment for established cases of tardive
dyskinesia, although some symptoms may partially or com-
pletely, if neuroleptic treatment is withdrawn. Neuroleptic treat-
ment, itself, however, may suppress (or partially suppress) the
signs and symptoms of the syndrome and thereby possibly mask the underlying disease process. The effect that symp-
tomatic suppression has upon the long-term course of the syn-
drome is unknown.

In light of these considerations, neuroleptics should be pre-
scribed in a manner that is most likely to minimize the occur-
rence of tardive dyskinesia. Chronic neuroleptic treatment
should generally be reserved for patients who suffer from a chronic
illness (see BOXED WARNING). The following contraindications are applied:
2.5 mg – D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No.
5 mg – FD&C Blue No.1 Aluminum Lake, D&C Yellow No.
10 mg – FD&C Yellow No. 6 Aluminum Lake.