PRESCRIBING INFORMATION

[Pr]FLUPHENAZINE

Fluphenazine Hydrochloride Tablets USP

1 mg, 2 mg, and 5 mg

Antipsychotic

AA PHARMA INC.
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Vaughan, Ontario
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Control Number: 156865

DATE OF PREPARATION:
July 9, 2012

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THERAPEUTIC CLASSIFICATION

Antipsychotic

PHARMACOLOGY

Phenothiazine derivatives appear to act on the hypothalamus, depressing various components of the mesodiencephalic activating system which is involved in the control of basal metabolism and body temperature, wakefulness, vasomotor tone, emesis and hormonal balance. In addition, the drugs exert a peripheral autonomic effect in varying degrees. However, the site and mode of action of the phenothiazine derivatives have not been completely elucidated.

In the treatment of psychotic disorders, fluphenazine, like other phenothiazine derivatives, alleviates many of the psychotic symptoms, although it does not substantially alter the basic psychotic process. The drug is primarily effective in reducing hostility, anxiety, agitation and hyperactivity; confusion, hallucinations and delusions are affected to a lesser degree. In general, the psychotic patient becomes more cooperative, more responsive to social situations, and more subject to basic therapy.

INDICATIONS

The management of manifestations of psychotic disorders; the treatment of behavioral disorders in adults.

CONTRAINDICATIONS

Comatose or depressed states due to CNS depressants; blood dyscrasias, bone marrow depression, liver damage. Hypersensitivity to fluphenazine; cross sensitivity to other phenothiazines may occur.

Phenothiazines are contraindicated in patients with suspected or established subcortical brain damage with or without hypothalmic damage, since a hyperthermic reaction with temperatures in excess of 40°C may occur in such patient, sometimes not until 14 to 16 hours after drug administration. Total body ice packing is recommended for such a reaction; antipyretics may also be useful.

Phenothiazine compounds should not be used in patients receiving large doses of hypnotics due to the possibility of potentiation.

Patients with pheochromocytoma, cerebrovascular or renal insufficiency, or severe cardiac reserve deficiency such as mitral insufficiency, as well as patients who have exhibited idiosyncrasy to other centrally-acting drugs may experience severe reactions to phenothiazine compounds and are particularly prone to hypotensive reactions. Fluphenazine is not recommended in these patients.

PRECAUTIONS

Phenothiazines may increase the effects of general anesthetics, opiates, barbiturates, alcohol and other CNS depressants as well as atropine and phosphorus insecticides.

Avoid epinephrine in the treatment of phenothiazine induced hypotension because phenothiazines may reverse epinephrine's action and thereby cause a further fall in blood pressure.

Hypotension, which is typically orthostatic, may occur especially in elderly and in alcoholic patients. This effect may be additive with other hypotensive agents. Exercise special care in those patients in whom a hypotensive crisis would be undesirable, such as those with arteriosclerosis or other cardiovascular diseases.

Psychotic patients on large doses of a phenothiazine drug who are undergoing surgery should be watched carefully for possible hypotensive phenomena. Moreover, it should be remembered that reduced amounts of anesthetics or CNS depressants may be required.

Prolongation of the QT interval, flattening and inversion of the T wave and appearance of a wave tentatively identified as a bifid T or a U wave have been observed in some patients receiving phenothiazines. These changes appear to be reversible and related to a disturbance in repolarization. Give phenothiazines cautiously to patients with heart disease.

Most reported cases of agranulocytosis associated with the administration of phenothiazine derivatives have occurred between the fourth and tenth week of treatment. Therefore, observe patients on prolonged therapy with particular care during that time for the appearance of such signs as sore throat, fever and weakness. If these symptoms appear, discontinue the drug and perform liver function tests. It is also advisable to perform WBC and differential counts and liver function tests periodically during therapy.

Phenothiazines have been associated with retinopathy and lenticular or corneal deposits. Discontinue fluphenazine if retinal changes are observed.

Use fluphenazine cautiously in patients with a history of seizures since grand mal convulsions have been known to occur.

The occasional increase in physical activity resulting from fluphenazine administration may augment the severity of anginal pain. Observe affected patients carefully and withdraw the drug if necessary.

Use with caution in patients exposed to extreme heat and in patients with a history of ulcer disease.

Monitor the renal function of patients on long-term therapy since elevation of BUN has been reported. If abnormal values are observed, discontinue the drug. Patients who may develop urinary retention should be carefully observed.

In general, phenothiazines do not produce psychic dependence. However, gastritis, nausea, vomiting, dizziness, and tremulousness have been reported following abrupt cessation of high dose therapy.

Paralytic ileus, even resulting in death, may occur, especially in the elderly. This possibility should be kept in mind and appropriate measures should be taken if constipation develops.

Endocrine and Metabolism:

Hyperglycemia: Diabetic ketoacidosis (DKA) has occurred in patients with no reported history of hyperglycemia. Patients should have baseline and periodic monitoring of blood glucose and body weight.

Hyperprolactinemia: Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone mineral density in both female and male subjects.

Genitourinary: Rare cases of priapism have been reported with antipsychotic use, such as FLUPHENAZINE. This adverse reaction, as with other psychotropic drugs, did not appear to be dose-dependent and did not correlate with the duration of treatment.

The safety and efficacy of fluphenazine in children have not been established, as there has been inadequate experience with the drug in this age group.

Special Populations, Pregnant Women:

Non-Teratogenic Effects: Neonates exposed to antipsychotic drugs (including FLUPHENAZINE) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

FLUPHENAZINE should not be used during pregnancy unless the expected benefits to the mother markedly outweigh the potential risks to the fetus.

Safe use of fluphenazine in human pregnancy has not been established. Therefore, it should not be administered to women of childbearing potential, particularly during the first trimester of pregnancy, unless the expected benefit to the patient outweighs the potential risk to the fetus.

Use during lactation should be avoided.

Where patients are participating in activities requiring complete mental alertness, such as driving an automobile or operating machinery, administer the phenothiazine cautiously, forewarn the patient, and increase the dosage gradually.

The antiemetic effect of fluphenazine can obscure signs of toxicity due to overdosage of other drugs, or mask the symptoms of disease.

Neutropenia, granulocytopenia and agranulocytosis have been reported during antipsychotic use. Therefore, it is recommended that patients have their complete blood count (CBC) tested prior to starting FLUPHENAZINE and then periodically throughout treatment.

Venous thromboembolism (VTE), including fatal pulmonary embolism, has been reported with antipsychotic drugs, including FLUPHENAZINE, in case reports and/or observational studies. When prescribing FLUPHENAZINE all potential risk factors for VTE should be identified and preventative measures undertaken.

ADVERSE EFFECTS

Adverse effects with different phenothiazines vary in type, frequency, and mechanism of occurrence, i.e., some are dose-related, while others involve individual patient sensitivity. Some adverse effects may be more likely to occur, or occur with greater intensity, in patients with special medical problems, e.g.,

patients with mitral insufficiency or pheochromocytoma have experienced severe hypotension following recommended doses of certain phenothiazines.

In general, members of the piperazine group of phenothiazines have more marked stimulating effects, are more likely to cause motor disorders associated with extrapyramidal reactions, particularly in children, but are less likely to cause blood dyscrasias, hypotension, tachycardia, and drowsiness than the members of the other phenothiazine groups.

Not all of the following adverse reactions have been reported with every phenothiazine derivative, but they have been reported with one or more, and should be borne in mind when drugs of this class are administered.

Behavioral reactions: oversedation; impaired psychomotor function; paradoxical effects, such as agitation, excitement, insomnia, bizarre dreams, aggravation of psychotic symptoms; toxic confusional states.

CNS: extrapyramidal reactions, including pseudoparkinsonism (with motor retardation, rigidity, mask-like facies, pill rolling and other tremors, drooling, shuffling gait); dystonic reactions (including perioral spasms, and trismus, tics, torticollis, oculogyric crises, protrusion of the tongue, difficulty swallowing, carpopedal spasm and opisthotonas of the back muscles); and akathisia. Persistent dyskinesias resistant to treatment have been reported, particularly in elderly patients with previous brain damage. In addition, altered EEG tracings, disturbed body temperature and lowering of the convulsive threshold have occurred. Dizziness has been reported.

Tardive dyskinesia may appear in some patients on long-term antipsychotic therapy, or may appear after drug therapy has been discontinued. The risk appears to be greater in elderly patients on high-dose therapy, especially females. The symptoms are persistent and in some patients appear to be irreversible.

The syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, chewing movements). Sometimes these may be accompanied by involuntary movements of extremities.

There is no known effective treatment for tardive dyskinesia; antiparkinsonian agents usually do not alleviate the symptoms of the syndrome. All antipsychotic agents should be discontinued if these symptoms appear. Should it be necessary to reinstitute treatment, or increase the dosage of the agent, or switch to a different antipsychotic agent, the syndrome may be masked. The physician may be able to reduce the risk of this syndrome by minimizing the unnecessary use of neuroleptics and reducing the dose or discontinuing the drug, if possible, when manifestations of the syndrome are recognized, particularly in patients over the age of 50. Fine vermicular movements of the tongue may be an early sign of the syndrome. If the medication is stopped at that time, the syndrome may not develop.

Autonomic nervous system: dry mouth, fainting, stuffy nose, photophobia, blurred vision, miosis, hypertension, hypotension (see “Precautions”) salivation, perspiration, headache.

Gastrointestinal: anorexia, increased appetite, gastric irritation, nausea, vomiting, constipation, paralytic ileus.

Endocrine system: altered libido, menstrual irregularities, lactation, false positive pregnancy tests, inhibition of ejaculation, gynecomastia, weight gain.

Skin: itching rash, hypertrophic papillae of the tongue, angioneurotic edema, erythema, allergic purpura, exfoliative dermatitis, contact dermatitis.

Cardiovascular effects: hypotension, tachycardia, ECG changes (see “Precautions”).

Blood dyscrasias: agranulocytosis, leukopenia, granulocytopenia, eosinophilia, thrombocytopenia, anemia, aplastic anemia, pancytopenia.

Allergic reactions: fever, laryngeal edema, angioneurotic edema, asthma.

Hepatotoxicity: jaundice, biliary stasis.

Urinary disturbances: retention, incontinence.

Abnormal pigmentation: Recently, a peculiar skin eye syndrome has been recognized as an adverse effect following long-term treatment with phenothiazines. This reaction is marked by progressive pigmentation of areas of skin or conjunctiva and/or discoloration of the exposed sclera and cornea. Opacities of the anterior lens and cornea described as irregular or stellate in shape have also been reported. Patients receiving higher doses of phenothiazines for prolonged periods should have periodic complete eye examinations.

Miscellaneous: Sudden unexpected and unexplained deaths have been reported in hospitalized psychotic patients receiving phenothiazines. Previous brain damage or seizures may be predisposing factors; high doses should be avoided in known seizure patients. Several patients have shown flare-ups of psychotic behavior patterns shortly before death. Autopsy findings have usually revealed acute fulminating pneumonia or pneumonitis, aspiration of gastric contents or intramyocardial lesions. The physician should therefore be alert to the possible development of "silent pneumonias".

The following have also occurred with the phenothiazines: systemic lupus erythematosus like syndrome, altered CSF proteins, cerebral edema.

Patients should be advised of the risk of severe constipation during FLUPHENAZINE treatment, and that they should tell their doctor if constipation occurs or worsens, as they may need laxatives.

OVERDOSE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Symptoms: Overdosage is usually signified by parkinsonism, hypotension and sedation.

Treatment: Essentially supportive and symptomatic; the drug should be discontinued or the dosage reduced, and in severe cases, vomiting should be induced or gastric lavage should be instituted if the patient is conscious. Maintain the airway by any means necessary. Hypotension calls for the immediate use of an i.v. vasopressor drug such as levarterenol bitartrate USP. Epinephrine should not be used, as a further lowering of blood pressure may result. Symptoms of parkinsonism may be treated with such agents as benztropine mesylate of diphenhydramine HCl. CNS symptoms of anticholinergic type toxic effects can be reversed by physostigmine salicylate.

DOSAGE

Mental disorders and behavioral problems: depending on severity and duration of symptoms, the daily dosage for psychotic patients may range initially from 2.5 to 10 mg in divided doses given at 6 to 8 hour intervals.

The smallest amount that will produce the desired results must be carefully determined for each individual, since the optimal dosage varies from patient to patient.

Treatment is best instituted with the initial dosage, which may be increased, if necessary, until the desired clinical effects are achieved. Daily dosages exceeding 20 mg should be used with caution. When symptoms are controlled, dosage can generally be reduced gradually to daily maintenance doses of 1 to 5 mg, often given as a single daily dose. Continued treatment is needed to achieve maximum therapeutic benefits; further adjustments in dosage may be necessary during the course of therapy to meet the patient's requirements.

For geriatric patients, the suggested starting dose is 1 to 2.5 mg daily, adjusted according to the response of the patient.

SUPPLIED

Each round film coated tablet contains; Fluphenazine Hydrochloride 1 mg (pink), identified 1; 2 mg (coral), identified 2; 5 mg (white), identified 5. Bottles of 100's.

PART III: CONSUMER INFORMATION

PrFLUPHENAZINE
Fluphenazine Hydrochloride Tablets USP

This leaflet is part III of a three-part "Product Monograph" published when FLUPHENAZINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FLUPHENAZINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

FLUPHENAZINE is used in the management of manifestations of psychotic disorders and the treatment of behavioural disorders in adults.

What it does:

FLUPHENAZINE is an antipsychotic medication which affects chemicals in the brain that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly how FLUPHENAZINE works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

You should not use FLUPHENAZINE if you have:

• An allergy to fluphenazine hydrochloride, to any of its ingredients or to phenothiazines

• A medical condition known as pheochromocytoma (a tumor of the adrenal gland)

• A severe heart or blood vessel disorder

• Severe kidney problems

• Had brain damage

• Liver disease

• Problems with your bone marrow

• A blood cell disorder such as anemia, low white blood cell counts, or low platelets

• Drowsiness, slow breathing, weak pulse

• Decreased alertness caused by taking certain medications or drinking alcohol

• You are going to receive anesthesia in the spine or for a region (such as an arm, leg or the lower part of your body)

What the medicinal ingredient is:

Fluphenazine hydrochloride

What the nonmedicinal ingredients are:

Carnauba Wax, Corn Starch, D & C Red # 30 Aluminum Lake 30 % (2 mg only), Erythrosine Lake 40 % (1 mg only), Hydroxypropyl Methylcellulose, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Purified water, Titanium Dioxide

What dosage forms it comes in:

Tablets: 1 mg, 2 mg, 5 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Studies with various medicines of the group to which FLUPHENAZINE belongs, when used in the elderly patients with dementia, have been associated with an increased rate of death. FLUPHENAZINE is not indicated in elderly patients with dementia.

BEFORE you use FLUPHENAZINE talk to your doctor or pharmacist if:

- You have heart disease, glaucoma or prostatic hypertrophy
- You are addicted to alcohol. You should not take FLUPHENAZINE if you are under the effects of alcohol.
- You are pregnant. FLUPHENAZINE should not be used during pregnancy unless your doctor considers the benefits to you markedly outweigh the potential risks to the fetus
- You are taking barbiturates, painkillers , narcotics or, antihistamines or other drugs that make you drowsy.
- You have any allergies to this drug or its ingredients
- You have or ever had a blackout or seizure
- You are breast feeding.
- You have or ever had ulcers.
- If you have risk factors for developing blood clots such as: s family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, or take oral contraceptives ("The Pill").

FLUPHENAZINE may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, especially during the first few days of therapy. You should be cautious when performing potentially hazardous tasks.

Effects on Newborns:
In some cases babies born to a mother taking FLUPHENAZINE during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

People who take FLUPHENAZINE are cautioned:

- Against exposure to extreme heat
- That drugs such as FLUPHENAZINE increase the toxicity of certain types of insecticides ("organophosphorous" insecticides) including insecticides for agriculture (farming), treating animals (flea and tick control) and for treating pests around the house and garden. Be cautious if you must use these products while taking FLUPHENAZINE.

INTERACTIONS WITH THIS MEDICATION

FLUPHENAZINE can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on FLUPHENAZINE therapy.

Tell your doctor about all your prescription and over-the-counter medications, vitamins, minerals, herbal products (such as St. John's Wort), and drugs prescribed by other doctors. Do not start a new medication without telling your doctor.

Before using FLUPHENAZINE, tell your doctor if you regularly use other medicines that make you sleepy (such as cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxants, and medicine for seizures, depression, or anxiety). You should not take FLUPHENAZINE if you have drowsiness caused by other medications.

Drugs that may interact with FLUPHENAZINE include:
anti-anxiety agents, antidepressants, muscle relaxants, anti-seizure medicine, high blood pressure medicine, cabergoline, metrizamide, guanethidine, guanadrel, grepafloxacin, sparfloxacin, lithium, cisapride, atropine-like drugs, narcotic pain relievers (e.g., codeine), drugs used to aid sleep, drowsiness-causing antihistamines (e.g., diphenhydramine), other drugs that may make you drowsy.

Many cough-and-cold products contain ingredients that may add a drowsiness effect. Before using cough-and-cold medications, ask your doctor or pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

This list is not complete and there may be other drugs that can interact with FLUPHENAZINE.

PROPER USE OF THIS MEDICATION

Take this medication by mouth exactly as prescribed. During the first few days your doctor may gradually increase your dose to allow your body to adjust to the medication. Do not take this more often or increase your dose without consulting your doctor. Your condition will not improve any faster but the risk of serious side effects will be increased. Do not stop taking this drug suddenly without your doctor's approval.

Your doctor will decide which dose is best for you.

Usual dose:

Mental disorders and behavioural problems: The usual dose is between 2.5 to 10 mg divided into 3-4 doses per day. For elderly patients a lower starting dose of 1 to 2.5 mg daily is usually used.

Once your symptoms are under control your doctor may lower your dose in order to find the lowest dose that best control your symptoms.

You must continue to take your medicine as long as your doctor tells you to. Do not stop taking it or change the dose even if you are feeling better. In order to help control your symptoms this medicine must be taken regularly.

For geriatric patients, the suggested starting dose is 1 to 2.5 mg daily, adjusted according to the response of the patient.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Overdose symptoms may include agitation, and confusion, drowsiness, dizziness, muscle stiffness or twitching, increased salivation, trouble swallowing, weakness, loss of balance or coordination, and fainting.

Missed Dose:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not double your dose to make up the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medications, FLUPHENAZINE may cause some side effects. These side effects may be minor and temporary. However, some may be serious and need medical attention.

Side effects may include: sweating, urinary incontinence, dizziness, drowsiness, dry mouth, nasal congestion, nausea and vomiting, headache, excitement, insomnia, bizarre dreams, an increase in saliva, tongue changes, changes in appetite (increased or decreased), stomach problems, inability to ejaculate, false positive pregnancy tests, skin rashes and redness, menstrual changes, change in libido, swelling of the breasts and milk production in both men and women, weight changes and blurred vision.

If any of these affects you severely, tell your doctor.

Your doctor should check your body weight before starting FLUPHENAZINE and continue to monitor it for as long as you are

being treated.

Your doctor should take blood tests before starting FLUPHENAZINE. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	**Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever			✓
	Neuroleptic Malignant Syndrome: any group of symptoms which may include high fever, sweating, stiff muscles, fast heartbeat, fast breathing and feeling confused, drowsy or agitated			✓
	Extrapyramidal Symptoms: muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.			✓
	Fast or irregular heartbeat, chest pain			✓
	Seizures or fits			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of penis			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek
	Tardive Dyskinesia: uncontrollable movements or twitches of the body, face, eyes or tongue, stretching the neck and body		✓	
	Low Blood Pressure: feeling of Lightheadedness or fainting especially when getting up from a lying or sitting position		✓	
	High Blood Pressure: headaches, vision disorders, nausea and vomiting		✓	
	Decreased sweating		✓	
	Jaundice: yellow colour to skin and eyes, dark urine		✓	
	Respiratory Infection: fever, flu-like symptoms, coughing, difficult or fast breathing		✓	
	New or worsening constipation		✓	
	Akathisia: a feeling of restlessness, inability to remain motionless		✓	
	Vision Changes: blurred vision, glaucoma or other eye disorder		✓	
	Increased Blood Sugar: frequent urination, thirst and hunger	✓		
	Worsening of psychotic symptoms			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek
	Toxic confusional state: symptoms include abnormal thoughts, hallucinations, delusions, changes in sleep patterns, confusion, anxiety, anger, speech that doesn't make sense, problems concentrating.			✓
	Inability to urinate		✓	
	Flu-like illness: symptoms include, fever, fatigue, muscle and joint pain		✓	
	Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		✓	
	Anemia: symptoms include fatigue, dizziness, shortness of breath, increased heart rate.	✓		
	Increased bleeding, bruising	✓		

This is not a complete list of side effects. For any unexpected effects while taking FLUPHENAZINE, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15 - 30°C (59-86°F). Keep container tightly closed. Protect from light.

Keep this and all medications out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This leaflet was prepared by AA Pharma Inc., Vaughan, Ontario, L4K 4N7.

Last revised: July 9, 2012