PRESCRIBING INFORMATION
PRODUCT MONOGRAPH

NEULEPTIL

Periciazine

Psychotropic Agent

ERFA
Canada 2012 Inc.

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Neuleptil®
®:Aventis Pharma
Periciazine
Psychotropic Agent

ACTION

Periciazine is a phenothiazine of the piperidine group. It has been shown to reduce pathologic arousal and affective tension in some psychotic patients, while the symptoms of abnormal mental integration are relatively unaffected.

It is a sedative phenothiazine with weak antipsychotic properties. It also has adrenolytic, anticholinergic metabolic and endocrine effects, and an action on the extrapyramidal system. Like other phenothiazines, it is presumed to act principally in the subcortical areas, by producing what has been described as a central adrenergic blockade.

INDICATIONS

As adjunctive medication in some psychotic patients, for the control of residual prevailing hostility, impulsiveness and aggressiveness.

CONTRAINDICATIONS

Circulatory collapse, altered states of consciousness or comatose states, particularly when they are due to intoxication with central depressant drugs such as alcohol, hypnotics, analgesics, narcotics, etc. It should also not be administered in association with spinal or regional anesthesia. Periciazine is contraindicated in patients with a history of blood dyscrasias, liver disease or hypersensitivity related to other phenothiazines.

WARNINGS

Geriatrics and Debilitated Patients: Particular care should be exercised when periciazine is given to elderly or debilitated patients as some appear to be unduly sensitive to the effects of the drug.

Elderly Patients with Dementia: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10- week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death in clinical trials with atypical antipsychotics were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic

drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

Risk of Stroke: In randomized clinical trials versus placebo performed in a population of elderly patients with dementia and treated with certain atypical antipsychotic drugs, a 3-fold increase of the risk of cerebrovascular events has been observed. The mechanism of such risk increase is not known. An increase in the risk with other antipsychotic drugs or other populations of patients cannot be excluded. NEULEPTIL should be used with caution in patients with stroke risk factors.

Neuroleptic phenothiazines may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalemia, and congenital or acquired (i.e. drug induced) QT prolongation. If the clinical situation permits, medical and laboratory evaluations should be performed to rule out possible risk factors before initiating treatment with a neuroleptic agent and as deemed necessary during treatment. (See also **ADVERSE REACTIONS**).

Occupational Hazards: Because drowsiness, slowing of reaction time or impaired judgment may occur, patients should generally not operate a motor vehicle or engage in dangerous activities while under the action of the drug.

Patients who have demonstrated a hypersensitivity reaction (e.g., blood dyscrasias, jaundice) with a phenothiazine should not be re-exposed to any phenothiazine unless, in the judgment of the physician, the potential benefits of treatment outweigh the possible hazards.

It should not be used in patients with convulsive disorders that are not receiving appropriate anticonvulsive medication.

Tardive Dyskinesia: As with all antipsychotic agents, tardive dyskinesia may appear in some patients on long-term therapy or after drug discontinuation. The syndrome is mainly characterized by rhythmical involuntary movements of the tongue, face, mouth or jaw. The manifestations may be permanent in some patients. The syndrome may be masked when treatment is reinstituted, when the dosage is increased or when a switch is made to a different antipsychotic drug. Periciazine should be prescribed in a manner that is most likely to minimize the risk of tardive dyskinesia. The lowest effective dose and the shortest duration of treatment should be used, and treatment should be discontinued at the earliest opportunity, or if a satisfactory response cannot be obtained. If the signs and symptoms of tardive dyskinesia appear during treatment, discontinuation of periciazine should be considered.

Neuroleptic Malignant Syndrome: Neuroleptic malignant syndrome (NMS) may occur in patients receiving antipsychotic drugs. NMS is characterized by hyperthermia, muscle rigidity, altered consciousness, and signs of autonomic instability including irregular blood pressure,

tachycardia, cardiac arrhythmias and diaphoresis. Additional signs may include elevated serum creatine kinase, myoglobinuria (rhabdomyolysis), acute renal failure and leukocytosis. Hyperthermia is often an early sign of this syndrome. Antipsychotic treatment should be withdrawn immediately and appropriate supportive therapy and careful monitoring instituted.

Cases of venous thromboembolism, sometimes fatal, have been reported with antipsychotic drugs. Therefore, NEULEPTIL should be used with caution in patients with risk factors for thromboembolism. (See also **ADVERSE REACTIONS**).

Pregnant Women:
Non-teratogenic effects: Neonates exposed to antipsychotic drugs including NEULEPTIL 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, various degrees of respiratory disorders ranging from tachypnoea to respiratory distress and bradycardia. Although these events occurred most often when other drugs such as psychotropic or antimuscarinic drugs were coadministered, they may also occur with antipsychotic use alone. Signs related to atropinic properties of phenothiazines such as meconium ileus, delayed meconium passage, abdominal bloating, tachycardia and feeding disorder in neonates can also occur. 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. Appropriate monitoring and treatment of neonates born to mothers receiving NEULEPTIL are recommended.

Since the safety of NEULEPTIL during pregnancy has not been established, NEULEPTIL should not be used during pregnancy or in women of child bearing potential unless the expected benefits to the mother markedly outweigh the potential risks to the fetus.

PRECAUTIONS

Periciazine may potentiate the action of other drugs; caution should therefore be exercised when it is prescribed with other phenothiazine derivatives or CNS depressants such as barbiturates, analgesics, narcotics or antihistamines, and the usual doses of these compounds should be reduced by at least half while the new treatment is being gradually introduced. Patients should also be advised against ingesting alcohol while under treatment.

Therapy should be initiated at low doses and caution used in patients with arteriosclerosis, cardiovascular disease, or other conditions where sudden hypotension is undesirable. Careful adjustments of dosage may be necessary if other drugs likely to cause postural hypotension are being administered concurrently. If hypotension should occur and a pressor agent is required, norepinephrine or phenylephrine may be used. Epinephrine should **not** be used since it may further lower blood pressure.

Because of its anticholinergic action, periciazine should be used with great caution in patients with glaucoma or prostatic hypertrophy. Paralytic ileus has occurred in patients, particularly in

the elderly, taking one or more drugs with anticholinergic action for extended periods. In such patients caution should be observed if constipation develops.

Retinal changes and abnormal skin pigmentation have been observed with phenothiazines and may occur after prolonged therapy. Discontinue therapy if these changes are observed.

It is generally advisable to perform periodic liver function tests during prolonged medication with periciazine. Periodic blood counts should also be performed, particularly during the first 2 or 3 months of therapy and patients should be observed for any signs or symptoms suggestive of blood dyscrasia.

To lessen the likelihood of adverse reactions related to drug accumulation, patients on long-term therapy, particularly on high doses, should be evaluated periodically to decide whether the maintenance dosage could be lowered or drug therapy discontinued. Sudden onset of severe CNS or vasomotor symptoms should be kept in mind.

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

Endocrine and Metabolism: Hyperglycaemia or intolerance to glucose has been reported in patients treated with NEULEPTIL. 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.
Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes who are started on NEULEPTIL, should get appropriate glycaemic monitoring during treatment. (See also **ADVERSE REACTIONS**).

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

Blood disorders: 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 NEULEPTIL and then periodically throughout treatment.

ADVERSE REACTIONS

Drowsiness, hypotension and extrapyramidal symptoms are the more frequently reported adverse reactions. Autonomic and psychomotor effects are usually observed at the beginning of treatment and frequently resolve while therapy is being continued or subside upon adjustment of dosage. Extrapyramidal reactions usually occur somewhat later and are mainly observed with higher dosages.

Adverse reactions 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 reactions may be more likely to occur, or occur with greater intensity in patients with special medical problem e.g., patients with mitral insufficiency or pheochromocytoma have experienced severe hypotension following recommended doses of certain phenothiazines.
Not all of the following adverse reactions have been observed 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: Drowsiness and impaired psychomotor activity are the most frequent initial untoward reactions but tend to subside within 1 to 3 weeks. Small initial doses will test tolerance to the drug. If a toxic-confusional state appears the medication should be stopped immediately. Paradoxical effects, such as agitation, insomnia, inversion of sleep, increased aggressiveness and activation of psychotic symptoms, have been occasionally observed.

Autonomic Nervous System: Postural hypotension and acute hypotensive crisis have been observed, particularly in the elderly, and occur more often at the beginning of treatment or when initial high dosages are used. These reactions may be avoided by testing the patient's tolerance with initial low doses. ECG changes and cardiac arrhythmias, including AV block paroxysmal tachycardia, and ventricular fibrillation, although not reported with periciazine, have been observed with some phenothiazines.

Predominant anticholinergic effects or sympathetic depression may be responsible for the following adverse reactions: tachycardia, blurred vision, aggravation of glaucoma, dry mouth (sometimes with oral infections and dental caries), nausea, vomiting, constipation, fecal impactation, paralytic ileus, perspiration, diarrhea, and nasal congestion. Changes in body temperature and hyperglycemia have been known to occur with phenothiazines.
CNS: The extrapyramidal reactions include: **Parkinsonism, dystonic reactions and akathisia.**

Parkinsonism occurs more frequently in patients receiving high doses and can usually be controlled by reducing the dose or temporarily discontinuing medication and, when necessary, by administering an antiparkinson drug. The dystonic reactions consist mainly of protrusion of the tongue, hyperextension of the neck and trunk, contraction of muscles of the neck and face, oculogyric crises, myolonic twitches and carpopedal spasm. Dystonic reactions are usually not dose-related but may be quite dramatic and require urgent treatment. Dystonic reactions have been reported with periciazine.

Tardive persistent dyskinesia resistant to treatment has been reported in connection with phenothiazine drugs (for detailed description see **WARNINGS**).

EEG changes, disturbed temperature regulation and seizures have also been reported. Periciazine is generally well tolerated by epileptics maintained on anticonvulsive therapy. However, epileptic attacks have been reported and it has not been established that periciazine effectively controls arousal or affective tension in these patients.

Allergic or Toxic Reactions: Agranulocytosis and other blood dyscrasias are among the more serious adverse reactions to phenothiazines. They may occur suddenly or follow a fall in blood

count, usually during the first 2 or 3 months of treatment. Cholestatic jaundice and liver injury, mainly of cholestatic or mixed type, are very rarely reported in patients treated with periciazine. Priapism has been very rarely reported in patients treated with periciazine.
Skin reactions, photosensitivity, asthma, laryngeal edema, angioneurotic edema, hyperpyrexia and other allergic reactions may also occur. Abnormal pigmentation, including comeal and lens deposits have been observed, usually when high doses of phenothiazines are given for prolonged periods.

Metabolic and Endocrine: Endocrine effects from phenothiazines such as delayed ovulation, menstrual irregularities, lactation, gynecomastia, changes in libido, inhibition of ejaculation, false positive pregnancy tests, weight gain and edemas, have been known to occur. Voracious appetite and weight gain have been reported in some patients on periciazine therapy. Intolerance to glucose, hyperglycemia have been reported (see **PRECAUTIONS**).

Miscellaneous: Unexpected sudden deaths, hypostatic pneumonia, and potentiation of other drugs have occurred during phenothiazine therapy. In some unexpected deaths, myocardial lesions have been observed. Previous brain damage or seizures may also be predisposing factors; high doses should be avoided in known seizure patients. Several patients have shown sudden exacerbations of psychotic behavior patterns shortly before death. Autopsy findings have also revealed acute fulminating pneumonia or pneumonitis and aspiration of gastric contents. The physician should therefore be alerted to the possible development of "silent pneumonias".

Cases of venous thromboembolism, including cases of pulmonary embolism, sometimes fatal, and cases of deep vein thrombosis have been reported with antipsychotic drugs (see also **WARNINGS**).

Very rare cases of **QT** interval prolongation have been reported. There have been isolated reports of sudden death, with possible causes of cardiac origin (see **WARNINGS**), as well as cases of unexplained sudden death, in patients receiving neuroleptic phenothiazines.

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

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Symptoms: In milder cases of phenothiazine overdosage the patient may be agitated, delirious and confused. Frequently he is lethargic or in a comatose state. Twitching dystonic movements or convulsions may be present and hypotension, cardiovascular collapse, arrhythmias and hypothermia might be observed.

Treatment: When indicated, gastric lavage can remove significant amounts of the drug. Careful supportive management is required until the patient is well out of drug-induced CNS depression. Shock, arrhythmia, respiratory failure and hypothermia are the main management problems. When a pressor agent is required, norepinephrine or phenylephrine may be used.

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

DOSAGE AND ADMINISTRATION

Adults: 5 to 20 mg in the morning and 10 to 40 mg in the evening. For maintenance therapy, the dosage should be reduced to the minimum effective dose. Lower doses of 2.5 to 15 mg in the morning, and 5 to 30 mg in the evening have been suggested.

For elderly patients the initial total daily dosage should be in the order of 5 mg and increased gradually as tolerated, until an adequate response is obtained. A daily dosage of more than 30 mg will rarely be needed.

Children and adolescents (5 years of age and over): 2.5 to 10 mg in the morning and 5 to 30 mg in the evening. These dosages approximate a daily dosage range of 1 to 3 mg/year of age.

In general, for both children and adults, the lower doses should not be exceeded initially. Subsequently, dosage may be gradually increased until the most effective level is reached. Caution is required when these dosages are exceeded.

Troublesome initial drowsiness has often been observed following periciazine administration. This may be obviated by giving the drug twice daily and reserving the major portion of the daily dosage for the evening.

Periciazine is not recommended in children under 5 years of age, since limited clinical experience is available.

AVAILABILITY OF DOSAGE FORMS

Capsules: Each light blue cap and white body opaque capsule, with black radial impression ‘’ERFA’’ on the cap and 5mg on the body contains: periciazine 5 mg. Nonmedicinal ingredients: calcium phosphate, croscarmellose sodium, FD&C Blue No 1, FD&C Red No 3, gelatin, magnesium stearate and titanium oxide. Tartrazine-free. Bottles of 100.

10 mg: Each light blue cap and white body opaque capsule, with black radial impression ‘’ERFA’’ on the cap and 10mg on the body contains: periciazine 10 mg. Nonmedicinal ingredients: calcium phosphate, croscarmellose sodium, FD&C Blue No 1, FD&C Red No 3, gelatin, magnesium stearate and titanium oxide. Tartrazine-free. Bottles of 100.

20 mg: Each capsule, with light blue cap and white body, with black radial impression ‘’ERFA’’ on the cap and 20 mg on the body opaque capsule contains: periciazine 20 mg Nonmedicinal ingredients: calcium phosphate, croscarmellose sodium, FD&C Blue No 1, FD&C Red No 3, gelatin, magnesium stearate and titanium oxide. Tartrazine-free. Bottles of 100.

Oral Drops: Each mL of liquid contains: periciazine 10 mg. Nonmedicinal ingredients: alcohol, ascorbic acid, caramel, glycerin, peppermint oil, purified water, sucrose and tartaric acid. Energy: 4.3 kJ (1.0 kcal)/mL. Tartrazine-free. Bottles of 100 mL with calibrated dropper.
Storage condition: Protect from light. Store between 15 – 30°C.

PART III: CONSUMER INFORMATION

Neuleptil
(Periciazine)

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

ABOUT THIS MEDICATION

What the medication is used for:

Neuleptil belongs to a group of medicines called "phenothiazines". It is used to control prevailing hostility, impulsiveness and aggressiveness when used with other medicines.

What it does:

Neuleptil 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 Neuleptil works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

You should not use Neuleptil if you have:

- **An allergy to periciazine, 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**
- **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:

Periciazine

What the nonmedicinal ingredients are:

Capsules: calcium phosphate, croscarmellose sodium, FD&C Blue No 1, FD&C Red No 3, gelatin, magnesium stearate and titanium oxide.

Oral drops: alcohol, ascorbic acid, caramel, glycerin, peppermint oil, purified water, sucrose and tartaric acid.

What dosage forms it comes in:

Capsules: 5mg, 10mg, 20mg
oral drops:10 mg/ml.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

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

- **You have heart disease, glaucoma or prostatic hypertrophy**
- **You are addicted to alcohol. You should not take Neuleptil if you are under the effects of alcohol.**
- **You are pregnant. Neuleptil 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, 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.**

Neuleptil 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 Neuleptil 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 Neuleptil are cautioned:

- **Against exposure to extreme heat**
- **That drugs such as Neuleptil 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 Neuleptil.**

INTERACTIONS WITH THIS MEDICATION

Neuleptil can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on Neuleptil 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 Neuleptil, 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 Neuleptil if you have drowsiness caused by other medications.

Drugs that may interact with Neuleptil 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 Neuleptil.

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:
Usual initial doses are:
Adults: 5 to 20 mg in the morning and 10 to 40 mg in the evening

Older adults: At first, 5 mg a day. Your doctor may increase your dose if needed. However, the dose is not usually more than 30 mg a day

Children 5 years of age and older: 2.5 to 10 mg taken in the morning, and 5 to 30 mg taken in the evening.

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, Neuleptil 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, 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 Neuleptil and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting Neuleptil. 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			✓
	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		✓	
	Seizures or fits			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of penis			✓
	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		✓	

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
	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	✓		

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

HOW TO STORE IT

Store this medication at room temperature between 15 and 30 oC away from heat and light. Do not store in the bathroom. 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 document plus the full product monograph, prepared for health professionals can be found at:
http://www.ECI2012.net
or by contacting the sponsor, Erfa Canada Inc. at:
1-800-922-3133

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