Product Monograph

Including Patient Medication Information

[Pr]PROCHLORAZINE

Prochlorperazine Maleate Tablets

For oral use

5 mg and 10 mg Prochlorperazine

USP

Antipsychotic/Antiemetic

AA Pharma Inc.
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Date of Authorization:
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Recent Major Label Changes

None at time of the most recent authorization	

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

PROCHLORAZINE (Prochlorperazine Maleate Tablets) is indicated for:

- the management of manifestations of psychotic disorders such as agitation, confusion, delusion, tension and anxiety.
- controlling nausea and vomiting due to stimulation of the chemoreceptor trigger zone.

In selected patients, prochlorperazine may be of value for the relief of excessive anxiety, accompanied by severe tension and agitation, associated with psychoneurotic or somatic conditions.

1.1. Pediatrics

Pediatrics (> 2 years and < 18 years of age): See 4.2. Recommended Dose and Dosage Adjustment and 7.1.3. Pediatrics.

Occasionally the patient may react to the drug with signs of restlessness and excitement; if this occurs, treatment should be discontinued.

Acute febrile illness or dehydration: In such patients, the drug should be used under close supervision and at low doses.

Pediatrics (< 2 years of age): Do not administer to children under 2 years of age unless potentially lifesaving. Do not administer to children under 9 kg of body weight.

1.2. Geriatrics

Geriatrics (> 65 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness. See 7.1.4. Geriatrics.

2. Contraindications

PROCHLORAZINE (Prochlorperazine Maleate Tablets), is contraindicated in

- Patients who are hypersensitive to this drug or a history of hypersensitivity to phenothiazine derivatives or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.
- The presence of circulatory collapse, altered states of consciousness or comatose states, particularly when these are due to intoxication with central depressant drugs (alcohol, hypnotics, narcotics).
- Severely depressed patients, in the presence of blood dyscrasias, liver disease, renal insufficiency, pheochromocytoma, or in patients with severe cardiovascular disorders.
- As with other phenothiazines, in patients with suspected or established subcortical brain damage, with or without hypothalamic damage, since a hyperthermic reaction with temperatures above 40°C may occur, sometimes not until 14 to 16 hours after drug administration.
- Patients receiving large doses of hypnotics, due to the possibility of potentiation.
- Children undergoing surgery.

3. Serious Warnings and Precautions Box

- **Increased mortality in geriatric patients with dementia**: Geriatric patients with dementia treated with antipsychotic drugs are at an increased risk of death compared to those treated with placebo. PROCHLORAZINE is not approved for use in geriatric patients with dementia.
- Neuroleptic malignant syndrome (NMS) is a rare, sometimes fatal, neurological disorder that has been reported in association with antipsychotic drugs including zuclopenthixol (see 8 Adverse Reactions).

4. Dosage and Administration

4.1. Dosing Considerations

Begin with the lowest recommended dosage. Adjust to response of the individual.

4.2. Recommended Dose and Dosage Adjustment

Adults

To control nausea, vomiting or excessive anxiety: Usually 5 to 10 mg, 3 or 4 times daily; in mild cases, a single dose of 5 to 10 mg is often adequate.

In psychiatry for moderate to severe conditions, the usual starting dosage is 10 mg 3 or 4 times a day; increase dosage gradually by 5 to 10 mg every 2 or 3 days until symptoms are controlled or adverse reactions intervene. Some patients respond satisfactorily on 50 to 75 mg per day. In more severe disturbances it may reach 100 to 150 mg a day. For maintenance therapy, the dosage should be reduced to the minimum effective dose.

Pediatrics

Daily dosage, administered in divided doses, should be based on body weight rather than on age, and should not be exceeded. Do not administer to children under 2 years of age or 9 kg of body weight. Occasionally the patient may react to the drug with signs of restlessness and excitement; if this occurs, treatment should be discontinued.

From 9 to 14 kg: 2.5 mg, 1 or 2 times a day, maximum 7.5 mg/day.

From 14 to 18 kg: 2.5 mg, 2 or 3 times a day, maximum 10 mg/day.

From 18 to 39 kg: 2.5 mg, 3 times a day, or 5 mg 2 times a day, maximum 15 mg/day.

Vomiting usually subsides after a single day of treatment.

In psychiatry: On the first day of treatment a dosage of 10 mg, in divided doses, should not be exceeded. The maximum total daily dosage reached by gradual increments should not exceed 20 mg for children of 2 to 5 years, and 25 mg for children of 6 to 12 years.

4.4 Administration

Tablets are for oral administration.

4.5. Missed Dose

If a dose is missed, the patient should take it as soon as it is recognized. If it is almost time for the next dose, skip the missed dose and continue with the next scheduled dose. The patient should be instructed not take 2 doses at the same time.

5. Overdose

Symptoms

Primarily extrapyramidal reactions, CNS depression which may vary from simple lethargy to coma. Agitation and restlessness may also occur. Other possible manifestations include convulsions, fever and autonomic reactions such as hypotension, dry mouth and ileus.

Treatment

Essentially symptomatic and supportive. Early gastric lavage may be helpful.

Maintain an open airway. If hypotension occurs, the standard measures for managing circulatory shock should be initiated; if a pressor agent is required give levarterenol or phenylephrine and **not** epinephrine as it may further depress the blood pressure. Extrapyramidal reactions should be treated with an antiparkinsonian agent.

Centrally-acting emetics will be ineffective because of prochlorperazine's antiemetic action. Limited experience indicates that phenothiazines are not dialyzable.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Oral	Tablet 5 mg and 10 mg of Prochlorperazine as Prochlorperazine maleate	Carnauba wax, croscarmellose sodium, dextrates and magnesium stearate; the film coating contains D&C yellow #10 aluminum lake 14-18%, hydroxypropyl methylcellulose, polyethylene glycol, sunset yellow aluminum lake 40%, titanium dioxide.

Description

PROCHLORAZINE 5 mg: Each orange, round, biconvex, film-coated tablet engraved 5 on one side contains prochlorperazine maleate equivalent to 5 mg prochlorperazine. Available in bottles of 100, 500 and 1000.

PROCHLORAZINE 10 mg: Each orange, round, biconvex, film-coated tablet engraved 10 on one side contains prochlorperazine maleate equivalent to 10 mg prochlorperazine. Available in bottles of 100, 500 and 1000.

7. Warnings and Precautions

See 3 Serious Warnings and Precautions Box.

General

The antiemetic action of prochlorperazine may mask the signs and symptoms of overdosage of other drugs and may obscure the diagnosis and treatment of other conditions such as brain tumour or intestinal obstruction. Therefore, the etiology of nausea and vomiting should be established before using the drug.

Patients receiving prochlorperazine should be cautioned against exposure to extreme heat or organophosphorous insecticides.

Carcinogenesis and Genotoxicity

Neuroleptic drugs elevate prolactin levels; the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin-dependent *in vitro,* a factor of potential importance if the prescription of these drugs is contemplated in a patient with a previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia and impotence have been reported, the clinical significance of elevated serum prolactin levels is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of neuroleptic drugs. Neither clinical studies, nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis; the available evidence is considered too limited to be conclusive at this time.

Cardiovascular

Hypotension and ECG changes, particularly non-specific and usually reversible Q and T wave distortions, have been associated with the administration of phenothiazines. Therefore, prochlorperazine should be used with caution in patients with compensated cardiovascular and cerebrovascular disorders.

Driving and Operating Machinery

The use of this drug may impair the mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery.

While taking PROCHLORAZINE, patients should be cautioned not to drive, operate dangerous machinery or engage in activities that require alertness or physical coordination if they are experiencing any of these effects.

Potentiation of the effects of alcohol may also occur.

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

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

Because of its anticholinergic action, prochlorperazine should be used with great caution in patients with prostatic hypertrophy.

Hematologic

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 PROCHLORAZINE and then periodically throughout treatment.

Monitoring and Laboratory Tests

On long-term therapy, particularly during the first 2 or 3 months, it is advisable to perform periodic liver function tests and blood counts as cholestatic jaundice and blood dyscrasias may occur, necessitating discontinuation of treatment. Renal function should be monitored and, if BUN becomes abnormal, treatment should be discontinued.

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.

Neurologic

The increased incidence of seizures, which occasionally occur in epileptics started on antipsychotic medication, may be controlled by increasing the dosage of their anticonvulsant. Patients with a familial history of seizures or febrile convulsions are more likely to develop seizures than those who have no such history.

Unexpected, sudden deaths have occurred in hospitalized patients treated with phenothiazines. Previous brain damage or seizures may predispose. High doses should be avoided in known seizure patients.

Sudden exacerbations of psychotic behaviour patterns occurred in several patients shortly before death.

The possibility of persistent tardive dyskinesia should also be borne in mind when patients are under long-term treatment.

Withdrawal Emergent Neurological Signs

Abrupt withdrawal after short-term administration of antipsychotic drugs does not generally pose problems. However, transient dyskinetic signs are experienced by some patients on maintenance therapy after abrupt withdrawal. The signs are very similar to those described under Tardive Dyskinesia, except for duration.

Although it is not known whether gradual withdrawal of antipsychotic drugs will decrease the incidence of withdrawal emergent neurological signs, gradual withdrawal would appear to be advisable.

Ophthalmologic

Retinal changes, lenticular and corneal deposits have been observed with other phenothiazines and may occur after prolonged therapy.

Because of its anticholinergic action, prochlorperazine should be used with great caution in patients with glaucoma.

Respiratory

Acute fulminating pneumonia or pneumonitis and aspiration of gastric contents were also observed. Therefore, the physician also should keep in mind the possible development of silent pneumonias.

Skin

Abnormal skin pigmentation have been observed with other phenothiazines and may occur after prolonged therapy.

7.1. Special Populations

7.1.1. Pregnancy

Safety during pregnancy has not been established. Therefore prochlorperazine should not be used during pregnancy unless the expected benefits to the mother markedly outweigh the potential risks to the fetus.

Non-Teratogenic Effects: Neonates exposed to antipsychotic drugs (including prochlorperazine) 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.

7.1.2. Breastfeeding

It is unknown if Prochlorperazine maleate is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

7.1.3. Pediatrics

The drug should not be used in children under 2 years unless potentially life-saving.

The extrapyramidal symptoms which can occur secondary to prochlorperazine may be confused with the CNS signs of an undiagnosed primary disease responsible for the vomiting, e.g. Reye's syndrome or other encephalopathy. The use of prochlorperazine should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome.

Children with an acute febrile illness or suffering from dehydration seem to be much more susceptible than adults to neuromuscular reactions, particularly dystonias. In such patients, the drug should be used under close supervision and at low doses.

7.1.4. Geriatrics

The incidence of adverse reactions may be greater in patients over 55 years of age, since the half-lives of antipsychotic drugs are often prolonged. To minimize this possibility, the maintenance dosage should be reduced to the lowest effective level as soon as possible after initial titration and periodically reviewed.

Since psychiatric syndromes in the elderly can be caused by drugs or organic disease, withdrawal of the precipitating drug or treatment of the medical condition should supersede initiation of antipsychotic medication. These agents should not be used for non-psychiatric conditions for which other drugs are available, since the elderly are especially prone to develop adverse effects from antipsychotic drugs.

8. Adverse Reactions

8.1. Adverse Reaction Overview

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 with greater intensity, in patients with special medical problems.

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.

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

Blood and lymphatic system disorders: Blood dyscrasias including leukopenia, agranulocytosis, pancytopenia, thrombocytopenic or non-thrombocytopenic purpura, eosinophilia, and anemia, have been associated with phenothiazine therapy. Routine blood counts are therefore advisable during prolonged therapy. If any soreness of the mouth, gums or throat or any symptoms of upper respiratory infection occur and confirmatory leukocyte count indicates cellular depression, therapy should be discontinued and other appropriate measures instituted immediately.

Cardiac disorders:

Hypotension

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. Should hypotension occur in patients receiving prochlorperazine and a vasopressor agent be required, i.v. levarterenol or phenylephrine should be used, and not epinephrine, since phenothiazine derivatives can reverse the pressor effect of the latter drug.

General disorders and administration site conditions:

Miscellaneous

The following adverse reactions have been reported in patients receiving phenothiazine derivatives: headache, asthma, laryngeal, cerebral and angioneurotic edema, altered cerebrospinal fluid proteins, systemic lupus erythematosus-like syndrome, hyperpyrexia, ECG and EEG changes and hypotension severe enough to cause fatal cardiac arrest. Skin pigmentation, epithelial keratopathy, lenticular and corneal deposits have been associated with long-term administration.

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 behaviour patterns shortly before deaths. Autopsy findings have usually revealed acute fulminating pneumonia or pneumonitis, aspiration of gastric contents or intramyocardial lesions.

Potentiation of CNS depressants (barbiturates, narcotics, analgesics, alcohol, antihistamines) may occur.

Hepatobiliary disorders: Cholestatic jaundice and biliary stasis may be encountered, particularly during the first months of therapy, and require immediate discontinuation of treatment.

Immune system disorders:

Allergic

Pruritus, dermatitis, rash, erythema, urticaria, seborrhea, eczema, exfoliative dermatitis, and photosensitivity. The possibility of an anaphylactoid reaction should be borne in mind.

Metabolism and nutrition disorders:

Metabolic and Endocrine

Anorexia, menstrual irregularities, impotence, and increased thirst, weight changes, increased appetite, peripheral edema, galactorrhea, gynecomastia, false positive pregnancy tests, and changes in libido have also occurred in patients receiving phenothiazine therapy.

Nervous system disorders:

Neurological

Extrapyramidal reactions including tremor, rigidity, akathisia, dystonia, dyskinesia, oculogyric crises, opisthotonos, hyperreflexia and sialorrhea. EEG changes, disturbed temperature regulation and seizures have also been encountered. Seizures have also been encountered.

Persistent Tardive Dyskinesia

As with other antipsychotic agents, tardive dyskinesia may occur in patients on long-term therapy or may be observed after drug therapy has been discontinued. The risk seems to be greater in elderly patients on high doses, 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 the extremities.

There is no known effective treatment for tardive dyskinesia; antiparkinsonian agents usually do not alleviate the symptoms of this syndrome. It is suggested that all antipsychotic agents 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. It has been reported that the fine vermicular movements of the tongue may be an early sign of the syndrome and if the medication is stopped at that time, the syndrome may not develop. The physician may be able to reduce the risk of this syndrome by minimizing the unnecessary use of neuroleptic drugs and reducing the dose or discontinuing the drug, if possible, when manifestations of this syndrome are recognized, particularly in patients over the age of 50.

Neuroleptic Malignant Syndrome

As with other neuroleptic drugs, a symptom complex sometimes referred to as neuroleptic malignant syndrome (NMS) may occur. Cardinal features of NMS are hyperpyrexia, muscle rigidity, altered mental status (including catatonic signs), and evidence of autonomic instability (irregular pulse or blood pressure). Additional signs may include elevated CPK, myoglobinuria (rhabdomyolysis), and acute renal failure.

NMS is potentially fatal and requires symptomatic treatment and immediate discontinuation of neuroleptic treatment.

Autonomic Nervous System

Dry mouth, nasal congestion, headache, nausea, constipation, tachycardia, hypotension, syncope, dizziness, blurred vision, vomiting, sweating and urinary incontinence have been observed.

Other autonomic reactions which have occurred with phenothiazines are salivation, polyuria, glaucoma, bladder paralysis, adynamic ileus, and fecal compaction.

Psychiatric disorders:

Behavioral

Sleep disturbances, drowsiness, fatigue, insomnia, and depression have been reported and may, in severe cases, necessitate reduction in dosage. As with other phenothiazine derivatives, reactivation or aggravation of psychotic processes may be encountered. Paradoxical effects such as agitation, anxiety, restlessness, excitement and bizarre dreams, have been observed.

9. Drug Interactions

9.3. Drug-Behaviour Interactions

The interaction of PROCHLORAZINE with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 2 – Established or Potential Drug-Drug Interactions

Non-proprietary name(s) of the drug product(s)	Source of evidence	Effect	Clinical comment
Anticholinergic Drugs	T	Effects of anticholinergic drugs may be potentiated	Paralytic ileus, even resulting in death, may occur, especially in the elderly. Caution should be observed if constipation develops.
Alcohol	T	Potentiation of the effects of alcohol may also occur.	See 7. Warnings and precautions, Driving and Operating Machinery
General anesthetics, opiates, barbiturates, and other CNS depressants	T	Phenothiazines may increase the effects	The doses of these drugs should be reduced if administered concomitantly with prochlorperazine.

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical; PBPK = Physiologically based pharmacokinetic modeling; popPK = Population pharmacokinetic modeling

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

Prochlorperazine is a piperazine phenothiazine derivative with antipsychotic, antiemetic and weak sedative activity.

10.2. Pharmacodynamics

Prochlorperazine has actions similar to those of other phenothiazine derivatives but appears to be less sedating and to have a weak propensity for causing hypotension or potentiating the effects of CNS depressants and anesthetics. However, it produces a high incidence of extrapyramidal reactions.

10.3. Pharmacokinetics

Absorption

Prochlorperazine is well absorbed from the gastrointestinal tract. Onset of action following oral administration is 30 to 40 minutes; 60 minutes for suppositories and 10 to 20 minutes after i.m. administration. Duration of action for all routes is 3 to 4 hours.

Distribution

Prochlorperazine distributes to most body tissues with high concentrations being distributed into liver and spleen.

Elimination

Prochlorperazine enters the enterohepatic circulation and is excreted chiefly in the feces.

11. Storage, Stability, and Disposal

Store ate room temperature 15°C to 30°C. Protect from light.

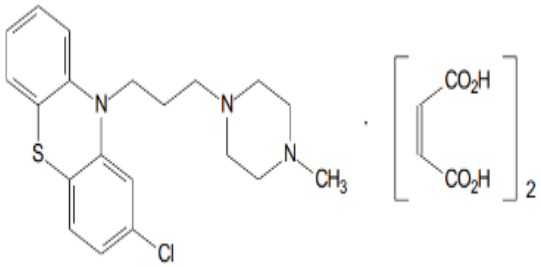
Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance:	Prochlorperazine Maleate
Chemical name:	10H-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl)-propyl]-, (Z)-2-butenedioate (1 : 2) 2-Chloro-10-[3-(4-methylpiperazin-1-yl) propyl] phenothiazine maleate (1 : 2)
Molecular formula and molecular mass:	$C_{20}H_{24}ClN_3S \cdot 2C_4H_4O_4$ and 606.09 g/mol

Structural formula:



Physicochemical properties:	Prochlorperazine maleate is white or pale yellow, crystalline powder. It is very slightly soluble in warm chloroform, practically insoluble in water and in alcohol. pKa= 8.21. No chiral centers are present in Prochlorperazine Maleate. Constant crystalline form is obtained.
Pharmaceutical standard:	USP

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

15. Microbiology

No microbiological information is required for this drug product.

16. Non-Clinical Toxicology

The clinical trial data on which the original indication was authorized is not available.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]PROCHLORAZINE

Prochlorperazine Maleate Tablets

This Patient Medication Information is written for the person who will be taking **PROCHLORAZINE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **PROCHLORAZINE**, talk to a healthcare professional.

Serious warnings and precautions box

Risk of death in elderly patients with dementia:

- PROCHLORAZINE belongs to a group of medicines called antipsychotics. These medicines have been linked to a higher rate of death when used in elderly patients with dementia (loss of memory and other mental abilities).
- PROCHLORAZINE is **not** to be used if you are elderly and have dementia.

Neuroleptic Malignant Syndrome (NMS): NMS is a rare but potentially life-threatening condition that has been reported with the use of antipsychotic medications like PROCHLORAZINE. Symptoms include:

- severe muscle stiffness or inflexibility with high fever,
- rapid or irregular heartbeat,
- sweating,
- state of confusion or reduced consciousness.

What PROCHLORAZINE is used for:

PROCHLORAZINE is used in adults and children (over 2 years of age and weighing over 9 kg) to:

- manage the symptoms of psychotic disorders such as:
  - agitation
  - confusion
  - delusion
  - tension and
  - anxiety
- control nausea and vomiting that is triggered by certain drugs or substances

How PROCHLORAZINE works:

PROCHLORAZINE is an antipsychotic medication which affects chemicals in the brain that allow communications between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin.

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

The ingredients in PROCHLORAZINE are:

Medicinal ingredient: Prochlorperazine maleate

Non-medicinal ingredients: Carnauba wax, croscarmellose sodium, dextrates and magnesium stearate; the film coating contains D&C yellow #10 aluminum lake 14-18%, hydroxypropyl methylcellulose, polyethylene glycol, sunset yellow aluminum lake 40%, and titanium dioxide.

PROCHLORAZINE comes in the following dosage form:

Tablets 5 mg and 10 mg

Do not use PROCHLORAZINE if:

- You are allergic to phenothiazine, phenothiazine derivatives or to any of the other ingredients in PROCHLORAZINE
- You have a medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- You have a severe heart or blood vessel problem
- You have kidney problems
- You have or had brain damage
- You have liver disease
- You have a blood cell disorder such as anemia, low white blood cell counts, or low platelets
- You have drowsiness, slow breathing, weak pulse
- You have decreased alertness or are in a deep state of prolonged unconsciousness (coma) caused by taking certain medications or drinking alcohol
- You are under 18 years of age and are going to have surgery
- You are taking hypnotics (medicines used to help with sleep)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROCHLORAZINE. Talk about any health conditions or problems you may have, including if you:

- have heart or blood vessel problems.
- suffer from an increased pressure within the eye(s) (glaucoma).
- have a condition that affects blood flow to your brain.
- have prostate problems (enlarged prostate gland in men).
- are addicted to alcohol. You should not take PROCHLORAZINE if you are under the effects of alcohol.
- are pregnant, think you might be pregnant or are planning to become pregnant. PROCHLORAZINE should not be used during pregnancy unless your healthcare professional considers the benefits to you markedly outweighs the potential risks to the fetus.
- have or have a family history of seizures (including those caused by fever). PROCHLORAZINE may make you more prone to seizures.
- are breastfeeding or planning to breast-feed. It is not known if PROCHLORAZINE can pass into your breast milk.
- are aged 55 years or above
- have liver problems.
- have or have ever had a low number of white blood cells (agranulocytosis).
- are dehydrated, or are exposed or will be exposed to extreme heat. PROCHLORAZINE may interfere with your body's ability to adjust to heat. Avoid becoming overheated or dehydrated (for example with vigorous exercise or exposure to extreme heat) while taking PROCHLORAZINE.

Other warnings you should know about:

Driving and using machines: PROCHLORAZINE may affect your mental and physical abilities. This may be more likely to occur when you start your treatment and when your dose is increased. Before you drive or do tasks that require special attention, wait until you know how you respond to PROCHLORAZINE. You should be cautious when driving a car or operating machinery.

Pregnancy: You should not take PROCHLORAZINE while you are pregnant or if you are planning on becoming pregnant unless you have talked to your healthcare professional about it. If you took PROCHLORAZINE at any time while you were pregnant or if you took it before you became pregnant, the following symptoms may happen in your newborn baby:

- shaking,
- stiffness in their muscles and/or weakness,
- sleepiness,
- agitation,
- breathing problems, or
- difficulty feeding.

Get medical help right away if your newborn has any of these symptoms.

Taking PROCHLORAZINE may also affect your pregnancy tests by producing false-positive pregnancy results.

Testing and check-ups: Your healthcare professional will monitor your health throughout your treatment. They may do this by performing certain tests before and periodically during your treatment. This will tell your healthcare professional how PROCHLORAZINE is affecting you. These tests may monitor:

- your blood glucose level;
- your body weight;
- the profile of your blood (e.g., red blood cell, white blood cell, and platelet counts);
- your liver and kidney function; and
- your eyes.

Hyperprolactinemia (increased levels of prolactin): PROCHLORAZINE can raise your levels of a hormone called "prolactin". This is measured with a blood test. Symptoms may include:

- In men:
  - swelling in the breast,
  - difficulty in getting or maintaining an erection or other sexual dysfunction.
- In women:
  - discomfort in the breasts,
  - leaking of milk from the breasts (even if not pregnant),
  - missing your menstrual period or other problems with your cycle.

If you have high levels of prolactin and a condition called hypogonadism, you may be at an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PROCHLORAZINE:

- alcohol. PROCHLORAZINE can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on PROCHLORAZINE therapy.
- general anesthetics, medicines used during surgery.
- barbiturates, medicines used to relax the body and help with sleeping.
- opiates, medicines used to relieve pain (e.g., codeine, hydromorphone and tramadol).
- muscle relaxants, medicines used to treat muscle spasms and back pain (e.g., suxamethonium, pancuronium and dantrolene).

How to take PROCHLORAZINE:

- Take PROCHLORAZINE exactly as your healthcare professional has told you.
- During the first few days of your treatment, your healthcare professional may gradually increase your dose. This is to allow your body to adjust and minimize side effects.
- Do not take PROCHLORAZINE more often or increase your dose without consulting your healthcare professional. Taking more than you should will not improve your condition any faster. Instead, you will increase your risk of serious side effects.
- Do not stop taking this medicine suddenly without your healthcare professional's approval.

Usual dose:

Your healthcare professional will decide on the best dose for you depending on the severity of your symptoms; and how you respond to your treatment. Your healthcare professional may change your dose based on how you respond to PROCHLORAZINE.

Adults:

- **For symptoms of psychotic disorders:** The usual dose is 10 mg three or four times a day.
- **For nausea and vomiting:** 5 mg to 10 mg three or four times a day.

Children (over 2 years of age and weighing over 9 kg):

- The usual dose is based on how much they weigh and given in divided doses.

Overdose:

Symptoms of an overdose with PROCHLORAZINE may include:

- muscle spasms
- restlessness
- drowsiness
- coma
- agitation
- restlessness
- convulsions
- fever
- low blood pressure
- dry mouth
- problems with your intestine

If you think you, or a person you are caring for, have taken too much PROCHLORAZINE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and take your next dose at your regularly scheduled time. Do NOT double your dose to make up for the missed dose.

Possible side effects from using PROCHLORAZINE:

These are not all the possible side effects you may have when taking PROCHLORAZINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with PROCHLORAZINE may include:

- sweating,
- urinary incontinence,
- increased urination,
- dizziness,
- drowsiness,
- dry mouth,
- increased salivation,
- changes in appetite,
- swelling in the extremities,
- skin pigmentation,
- nasal congestion,
- nausea and vomiting,
- headache,
- menstrual changes,
- change in libido,
- trouble getting or keeping an erection,
- swelling of the breasts and milk production in both men and women,
- weight changes,
- lack of energy,
- trouble falling asleep and/or staying asleep,
- abnormal dreams, and
- blurred vision.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Unknown			
Akathisia: a feeling of restlessness, inability to remain motionless		✓	
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever, asthma, wheezing, feeling sick to your stomach, itchiness, fatigue, fever			✓
Behavioural changes (including worsening of psychotic symptoms): hallucinations, delusions, changes in sleep patterns, confusion, depression, anxiety, anger, restlessness, problems			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
concentrating, disorientation, or agitation			
Blood disorders (low blood platelet, low white blood cell, and/or low red blood cell counts): frequent infection with fever, chills, soreness of the mouth, gums, or throat, fatigue, aches, pains, flu-like symptoms, paleness of the skin, rapid heart rate, shortness of breath, bruising easily, or heavy bleeding			✓
Extrapyramidal Symptoms: muscle stiffness, body spasm, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want, masklike face (appears to lack emotion), tremors, drooling, or dragging feet as you walk, difficultly swallowing, a feeling of restlessness, or inability to remain motionless			✓
Priapism (persistent and painful erection of the penis lasting longer than 4 hours)			✓
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	✓		
Hyperprolactinemia (increased levels of prolactin): In men: swelling in the breast, difficulty in getting or maintaining an erection, or other sexual dysfunction. In women: discomfort in the breasts, leaking of milk from the breasts (even if not pregnant), or missing your menstrual period or other problems with your cycle		✓	
Hypertension (high blood pressure): headaches, vision disorders, nausea, vomiting, shortness of breath, fatigue, dizziness, fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
and skin, racing pulse, or heart palpitations			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up)		✓	
Liver problems (including biliary stasis, cholestatic jaundice): upper right abdominal pain, pain in the back, nausea, vomiting, yellowing of the skin and white of eyes, dark urine, light coloured stool, or itching all over your body			✓
Neuroleptic Malignant Syndrome (NMS): pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion, or reduced consciousness			✓
Respiratory Infection: fever, flu-like symptoms, coughing, difficult or fast breathing		✓	
Seizures (fits): loss of consciousness with uncontrollable shaking.			✓
Tachycardia (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		✓	
Tardive Dyskinesia: uncontrollable, unusual, or abnormal movements, muscle twitches of the body, face, eyes or tongue, or stretching the neck and body		✓	
Eye problems: increased pressure in the eye, sensitivity to light, eye pain, headache, vision changes (such as blurred vision, halos around lights, glare, distorted vision, dark or blind spots in the center of your vision, or difficulty with depth perception), swelling or redness in or around the eye		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Exfoliative dermatitis (severe inflammation of the skin): red and peeling skin, scaling, crusting lesions, thickened skin, itching, swollen lymph nodes, fever, malaise, secondary infections (viral or bacterial)			✓
Lupus erythematosus-like syndrome: pain and swelling in the joints, skin rash, fatigue, fever		✓	
Overheating/dehydration (dry mouth, excessive thirst): thirst, headache, loss of appetite, feel tired and weak, lack of sweating, decreased blood pressure and urine, dark yellow urine	✓		
Paralytic ileus (muscles that move food through the intestines are paralyzed): new or worsening constipation, nausea, vomiting, dehydration, gas, or abdominal pain		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature 15°C to 30°C.

Protect from light.

Do not use after the expiry date shown on the bottle.

Keep out of reach and sight of children.

If you want more information about PROCHLORAZINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (http://www.aapharma.ca/en/); or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc. 1165 Creditstone Road Unit #1, Vaughan, Ontario L4K 4N7.

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