

PROPERAZINE TABLET 5MG

Each tablet contains -
Prochlorperazine maleate 5 mg

Pharmacodynamics:

Prochlorperazine has a wide range of activity arising from its depressant actions on the central nervous system and its alpha-adrenergic blocking and weaker anti-cholinergic activities. It is a dopamine inhibitor, it inhibits prolactin-release inhibitory factor, considered to be dopamine, thus stimulating the release of prolactin. The turnover of dopamine in the brain is also increased. Prochlorperazine possesses sedative and tranquillising properties but patients usually develop tolerance rapidly to the sedation. It has anti-emetic, anti-pruritic and weak anti-histamine properties and inhibit the heat regulating centre so that the patient tends to acquire the temperature of his surroundings. Prochlorperazine produces direct effects on the heart and blood vessels and also indirect ones through actions on CNS and autonomic reflexes. Hypotension is primarily due to inhibition of centrally mediated pressor effects but peripheral alpha-adrenergic blockage may also play a role. There is also a direct depressant action on the heart. The drug has a vasodilating action due to both its effects on the autonomic nervous system and a direct action on blood vessels.

Pharmacokinetics:

Prochlorperazine is well absorbed from the gastrointestinal tract. From 60 to 70% of an administered dose is rapidly removed from the portal circulation by the liver and there is a very active enterohepatic circulation. Fecal excretion of prochlorperazine is significant. A reciprocal relationship exists between the amounts excreted in the faeces and the urine. After absorption, it is rapidly distributed in all body tissues. Brain concentrations are relatively low compared to those in other organs, but considerably higher than in plasma; the highest concentrations of the drug is found in the lung, followed by the liver, the adrenal gland, and the spleen.

Indications:

For control of severe nausea and vomiting and non-psychotic anxiety.

Contraindications:

It is contraindicated in greatly depressed states due to central nervous system depressants and in the presence of bone marrow depression. It is also contraindicated in children under 2 years of age or under 20 lbs in weight. It should not be used in children for conditions for which dosage has not been established.

Side Effects / Adverse Reactions:

Drowsiness, dizziness, amenorrhea, blurred vision, skin reactions and hypotension may occur. Cholestatic jaundice has occurred. Leukopenia and agranulocytosis have also occurred. Neuro-ocular reactions characterised by motor restlessness, be of the dystonic type or may resemble parkinsonism are observed. Symptoms of motor restlessness may include agitation, jitteriness and sometimes insomnia. Symptoms of dystonia may include spasm of the neck muscles, sometimes progressing to torticollis; extensor rigidity of back muscles, sometimes progressing to opisthotonos; carpopedal spasm, trismus, swallowing difficulty, oculogyric crisis and protrusion of the tongue. Symptoms of pseudo-parkinsonism may include mask-like facies; drooling; tremors; pillrolling motion; cogwheel rigidity and shuffling gait. As with all antipsychotic agents, tardive dyskinesia may appear in some patients on long term therapy. This condition appears in all age groups. However, 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 characterised by rhythmic involuntary movements of the tongue, face, mouth or jaw. Sometimes these may be accompanied by involuntary movements of extremities.

Precautions / Warnings:

The extrapyramidal symptoms which can occur secondary to prochlorperazine may be confused with the central nervous system signs of an undiagnosed primary disease responsible for the vomiting, e.g. Reye's syndrome or other encephalopathy. The use of prochlorperazine and other potential hepatotoxins should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome. When prochlorperazine is used with cancer chemotherapeutic drugs, vomiting as a sign of the toxicity of these agents may be obscured by the antiemetic effect of prochlorperazine. Phenothiazines can diminish the effect of oral anticoagulants. Thiazide diuretics may accentuate the orthostatic hypotension that may occur with phenothiazines. Antihypertensive effects of guanethidine and related compounds may be counteracted when phenothiazines are used concomitantly. Concomitant administration of propranolol with phenothiazines results in increased plasma levels of both drugs. Patients with bone marrow depression or who have previously demonstrated a hypersensitivity reaction (e.g., blood dyscrasias, jaundice) with a phenothiazine should not receive any phenothiazine, including prochlorperazine, unless in the judgement of the physician the potential benefits of treatment outweigh the possible hazards. Prochlorperazine may impair mental and/or physical abilities, especially during the first few days of therapy. Therefore, caution patients about activities requiring alertness (e.g., operating vehicles or machinery). The antiemetic action of prochlorperazine may mask the signs and symptoms of overdose of other drugs and may obscure the diagnosis and treatment of other conditions such as intestinal obstruction, brain tumor and Reye's syndrome. Aspiration of vomitus has occurred in a few post-surgical patients who have received prochlorperazine as an antiemetic. Although no causal relationship has been established, this possibility should be borne in mind during surgical aftercare. As with all drugs which exert an anticholinergic effect and/or cause mydriasis, prochlorperazine should be used with caution in patients with glaucoma.

Because phenothiazines may interfere with thermoregulatory mechanisms, use with caution in persons who will be exposed to extreme heat. Phenothiazines can produce alpha-adrenergic blockade. The presence of phenothiazines may produce false-positive phenyleketonuria (PKU) test results.

Drug Interactions:

Safety for the use of prochlorperazine is used with cancer chemotherapeutic drugs, vomiting as a sign of the toxicity of these agents may be obscured by the antiemetic effect of prochlorperazine. Phenothiazines can diminish the effect of oral anticoagulants. Thiazide diuretics may accentuate the orthostatic hypotension that may occur with phenothiazines. Antihypertensive effects of guanethidine and related compounds may be counteracted when phenothiazines are used concomitantly. Concomitant administration of propranolol with phenothiazines results in increased plasma levels of both drugs.

Use in Pregnancy and Lactation:

Safety for the use of prochlorperazine during pregnancy has not been established. Therefore, prochlorperazine is not recommended for use in pregnant patients except in cases of severe nausea and vomiting that are so serious and intractable that, in the judgement of the physician, drug intervention is required and potential benefits outweigh possible hazards. There have been reported instances of prolonged jaundice, extrapyramidal signs, hyperreflexia or hyporeflexia in new born infants whose mothers received phenothiazines. There is evidence that phenothiazines are excreted in the breast milk of nursing mothers. Caution should be exercised when prochlorperazine is administered to a nursing woman.

Dosage:

Route of administration - Oral
Adults: Dosage should be tailored to the individual response, carefully monitored, and dosage adjusted accordingly. Dosage should be increased more gradually in elderly patients.

To control severe nausea and vomiting: 5 mg or 10 mg 3 or 4 times daily.

Non-psychotic anxiety: 5 mg or 10 mg 3 or 4 times daily.

Children: Children seem more prone to develop extrapyramidal reactions, even on moderate doses. Therefore the lowest effective dose should be used. Occasionally the patient may react to the drug with signs of restlessness and excitement, if this occurs additional doses should not be administered.

1. Severe nausea and vomiting: Prochlorperazine should not be used in children under 9 kg in weight or 2 years of age. It should not be used in conditions for which children dosages have not been established.

Weight	Usual Dosage	Not to exceed
under 9 kg	not recommended	
9 - 13.2 kg	2.5 mg 1 or 2 times daily	7.5 mg per day
13.5 - 17.5 kg	2.5 mg 2 or 3 times daily	10 mg per day
18 - 38.5 kg	2.5 mg 3 times daily or 5 mg 2 times daily	15 mg per day

2. In psychotic children: for children 2 to 12 years starting dosage is 2.5 mg 2 or 3 times daily.

Do not give more than 10 mg the first day. Then increase dosage according to patient response.

For ages 2 - 5: total daily dosage usually does not exceed 20 mg.

For ages 6 - 12: total daily dosage usually does not exceed 25 mg.

For ages 13 - 17: total daily dosage usually does not exceed 30 mg.

For ages 18 - 65: total daily dosage usually does not exceed 30 mg.

For ages 66 - 75: total daily dosage usually does not exceed 25 mg.

For ages 76 - 85: total daily dosage usually does not exceed 20 mg.

For ages 86 - 95: total daily dosage usually does not exceed 15 mg.

For ages 96 - 105: total daily dosage usually does not exceed 10 mg.

For ages 106 - 115: total daily dosage usually does not exceed 5 mg.

For ages 116 - 125: total daily dosage usually does not exceed 5 mg.

For ages 126 - 135: total daily dosage usually does not exceed 5 mg.

For ages 136 - 145: total daily dosage usually does not exceed 5 mg.

For ages 146 - 155: total daily dosage usually does not exceed 5 mg.

For ages 156 - 165: total daily dosage usually does not exceed 5 mg.

For ages 166 - 175: total daily dosage usually does not exceed 5 mg.

For ages 176 - 185: total daily dosage usually does not exceed 5 mg.

For ages 186 - 195: total daily dosage usually does not exceed 5 mg.

For ages 196 - 205: total daily dosage usually does not exceed 5 mg.

For ages 206 - 215: total daily dosage usually does not exceed 5 mg.

For ages 216 - 225: total daily dosage usually does not exceed 5 mg.

For ages 226 - 235: total daily dosage usually does not exceed 5 mg.

For ages 236 - 245: total daily dosage usually does not exceed 5 mg.

For ages 246 - 255: total daily dosage usually does not exceed 5 mg.

For ages 256 - 265: total daily dosage usually does not exceed 5 mg.

For ages 266 - 275: total daily dosage usually does not exceed 5 mg.

For ages 276 - 285: total daily dosage usually does not exceed 5 mg.

For ages 286 - 295: total daily dosage usually does not exceed 5 mg.

For ages 296 - 305: total daily dosage usually does not exceed 5 mg.

For ages 306 - 315: total daily dosage usually does not exceed 5 mg.

For ages 316 - 325: total daily dosage usually does not exceed 5 mg.

For ages 326 - 335: total daily dosage usually does not exceed 5 mg.

For ages 336 - 345: total daily dosage usually does not exceed 5 mg.

For ages 346 - 355: total daily dosage usually does not exceed 5 mg.

For ages 356 - 365: total daily dosage usually does not exceed 5 mg.

For ages 366 - 375: total daily dosage usually does not exceed 5 mg.

For ages 376 - 385: total daily dosage usually does not exceed 5 mg.

For ages 386 - 395: total daily dosage usually does not exceed 5 mg.

For ages 396 - 405: total daily dosage usually does not exceed 5 mg.

For ages 406 - 415: total daily dosage usually does not exceed 5 mg.

For ages 416 - 425: total daily dosage usually does not exceed 5 mg.

For ages 426 - 435: total daily dosage usually does not exceed 5 mg.

For ages 436 - 445: total daily dosage usually does not exceed 5 mg.

For ages 446 - 455: total daily dosage usually does not exceed 5 mg.

For ages 456 - 465: total daily dosage usually does not exceed 5 mg.

For ages 466 - 475: total daily dosage usually does not exceed 5 mg.

For ages 476 - 485: total daily dosage usually does not exceed 5 mg.

For ages 486 - 495: total daily dosage usually does not exceed 5 mg.

For ages 496 - 505: total daily dosage usually does not exceed 5 mg.

For ages 506 - 515: total daily dosage usually does not exceed 5 mg.

For ages 516 - 525: total daily dosage usually does not exceed 5 mg.

For ages 526 - 535: total daily dosage usually does not exceed 5 mg.

For ages 536 - 545: total daily dosage usually does not exceed 5 mg.

For ages 546 - 555: total daily dosage usually does not exceed 5 mg.

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