

IDAMAN PHARMA CHLORPROMAZINE TABLET 100MG

DESCRIPTION

Chlorpromazine Tablet 100mg

Clean, dry, uniform, round, biconvex, even edged, film coated tablets, scored on one side and white to off white in colour.

Each tablet contains:

Chlorpromazine Hydrochloride 100 mg.

PHARMACODYNAMICS

Antipsychotic - Chlorpromazine is thought to improve psychotic syndrome by blocking postsynaptic dopamine receptors in the brain. Chlorpromazine also produces an alpha-adrenergic blocking effect and depresses the release of hypothalamic, pituitary and hypophyseal hormones.

Antiemetic - Chlorpromazine inhibits the medullary chemoreceptor trigger zone.

Sedative - Chlorpromazine is thought to cause indirect reduction of stimuli to the brain stem reticular system.

PHARMACOKINETICS

Metabolism : Hepatic

Elimination : Primarily renal; biliary

In dialysis - Phenothiazines are not successfully dialyzed.

INDICATIONS

Chlorpromazine is widely used in the management of psychotic conditions. It controls excitement, agitation, and other psychomotor disturbances in schizophrenic patients and reduces the manic phase of manic - depressive conditions. It is used to control hyperkinetic states and aggression and is sometimes given in other psychiatric conditions for the control of anxiety and tension. Within an hour of a dose by mouth, patients become apathetic, drowsy and occasionally euphoric.

Chlorpromazine is anti-emetic and is used to control the nausea and vomiting of a variety of diseases and that caused by various drugs. The sedative and anti-emetic properties of chlorpromazine are useful in the treatment of drug dependence. Post-operative nausea and vomiting is reduced by chlorpromazine.

Since analgesic requirements are reduced by chlorpromazine, it is used as an adjunct in the management of severe pain, especially in malignant diseases.

RECOMMENDED DOSAGE

Dosage varies both with the individual and with the purpose for which the drug is being used. In most patient's oral treatment may be used from the start, commencing with a dosage of 25 to 50 mg thrice daily and increasing as necessary. The usual daily maintenance dose ranges from 25 to 100 mg thrice daily.

Psychotic patients may require daily doses of up to 1g or more. In the treatment of mild alcohol withdrawal, agitated patients may be given 25 to 50 mg twice daily by mouth. Patients with less severe withdrawal symptoms may be given 30 to 75 mg daily in divided doses by mouth. Chlorpromazine should not be given to stuporous patients.

Paediatric use of the tablets is not recommended.

ROUTE OF ADMINISTRATION: Oral

CONTRAINDICATIONS

Chlorpromazine is contraindicated in comatose patients, particularly those under the influence of alcohol, barbiturates, narcotics, or other central nervous system depressants and in patients with bone marrow depression. Where possible it should not be given in conjunction with drugs that might cause leucopenia such as phenylbutazone and the thiouracil derivatives.

If chlorpromazine is used in obstetrics, it is recommended that it should not be given until labour is established and the cervix dilated 3 to 4 cm.

WARNINGS AND PRECAUTIONS

Chlorpromazine should be used with caution in patients with cardiovascular or respiratory disease, pheochromocytoma or other conditions in which a sudden drop in blood pressure would be undesirable. Blood pressure of patients undergoing surgery should be carefully monitored; if it is used in conjunction with other drugs likely to cause postural hypotension an adjustment of dosage may be necessary. Patients who have demonstrated a severe hypersensitivity reaction such as jaundice should not be exposed to any phenothiazines unless absolutely necessary. Cross sensitivity does occur. Phenothiazines should be used with care in patients with Parkinsonism; the anti-Parkinsonian action of levodopa may be diminished by concurrent administration of phenothiazines.

The anti-emetic actions of chlorpromazine may mask the symptoms of disorders such as gastro-intestinal obstruction. Chlorpromazine should be given with caution in extremes of temperature owing to its impairment of the body temperature regulating mechanism.

Chlorpromazine may impair alertness especially during the first few days of treatment.

Withdrawal symptoms including nausea, vomiting, gastritis and tremors may occur following the abrupt discontinuation of large doses. Patients should be examined periodically for abnormal skin pigmentation or eye changes and chlorpromazine withheld if necessary. Chlorpromazine should be used with care in the elderly and debilitated. Drowsiness is often experienced at the start of treatment with chlorpromazine and patients should be advised not to take charge of vehicles or other machinery during this period. Avoid alcohol or other CNS depressants during therapy. Do not take within 2 hours, antacids or diarrhoeal medications. Caution when getting up suddenly from a lying or sitting position. Check with physician if restlessness or excitement should occur. Caution if any kind of surgery, dental treatment or emergency treatment is required.

Avoid photosensitivity of skin; by avoiding too much sun or use of sunlamp. Relieve dryness of mouth, using sugarless gum or candy, ice or saliva substitute for relief; check with physician or dentist if dry mouth continues for more than 2 weeks.

INTERACTIONS WITH OTHER MEDICAMENTS

Be aware of the drug interaction and consequently their effects between chlorpromazine and the following: -

Alcohol, CNS depressants, amphetamines, antacid or antidiarrheal suspension, anticoagulants, anticonvulsants, antidyskinetics, antimuscarinics especially atropine and related compounds, ephedrine, guanethidine and related compounds, levodopa, metrizamide, metoclopramide, MAO inhibitors or tricyclic anti-depressants. Ototoxic drugs especially ototoxic antibiotics and propranolol.

INCOMPATIBILITIES

Chlorpromazine hydrochloride is also incompatible with ampicillin, atropine sulphate, benzylpenicillin, chloramphenicol, heparin, hydrocortisone hydrogen succinate, metaraminol, methicillin, oxytetracycline, tetracycline, thiopentone sodium and Vitamins B and C Injection.

PREGNANCY AND LACTATION

Prolonged jaundice, hypo - or hyperreflexia, and extrapyramidal effects have been reported in the neonates of mothers who received phenothiazines near term. Small amounts of some phenothiazines have been found in breast milk. Drowsiness may occur in the baby. Most phenothiazines increase prolactin secretion in the mother. Risk-benefit is to be considered for use during pregnancy / breast-feeding.

Neonates exposed to antipsychotic drugs 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 hospitalisation CHLORPROMAZINE TABLET 100MG should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

SIDE EFFECTS

The side-effects of chlorpromazine include drowsiness, dryness of the mouth, nasal congestion, postural hypotension, lowering of body temperature (occasionally pyrexia), tachycardia, arrhythmias, agitation, insomnia, depression, miosis and mydriasis, oedema periorbital, convulsions, photosensitivity, skin rashes, and inhibition of ejaculation.

Jaundice of the obstructive type, and considered to be allergic in origin, has occurred in patients receiving chlorpromazine; it does not appear to be dose - related and is usually readily reversible. Chronic constipation and faecal impaction have also occurred. Various haematological reactions including agranulocytosis, leucopenia, leucocytosis, and haemolytic anaemia have occurred in patients taking chlorpromazine. It is advisable to be aware of symptoms such as sore throat or fever and to institute white cell counts should they appear. Extrapyramidal dysfunction occurs in patients receiving phenothiazines and is largely reversible by lowering the dose, or discontinuing therapy.

Allergic reactions include urticaria, photosensitisation and exfoliative dermatitis.

The administration of large doses of chlorpromazine for prolonged periods can lead to the development of a purplish pigmentation of exposed areas of the skin and more frequently, to the deposition of pigment in the eyes. Corneal and lens opacities have been observed in some patients.

Chlorpromazine and the other phenothiazines alter endocrine function. Patients have experienced amenorrhoea, galactorrhoea, gynaecomastia and weight gain and there have been reports of hyperglycaemia and diabetes mellitus. There have also been reports of raised serum cholesterol concentrations.

TREATMENT OF ADVERSE EFFECTS

In severe overdosage the stomach should be emptied by aspiration and lavage. Emetics should not be used. To counter acute hypotension the patient should be placed in the head-down position. Some sources have advocated the cautious intravenous administration of the alpha adrenergic sympathomimetics, noradrenaline and phenylephrine (not adrenaline or other pressor amines), but other sources specifically contraindicate the use of all sympathomimetics. In general, they are probably neither desirable nor necessary.

The central nervous depression should generally be allowed to recover naturally. The low body temperature should also be allowed to recover naturally unless there is any danger of cardiac arrhythmias being induced.

Severe extrapyramidal reactions should be treated with a slow intravenous injection of anti-Parkinsonian agents, such as benztropine mesylate, procyclidine hydrochloride, or some anti - histamines, such as diphenhydramine hydrochloride. Diazepam may also be effective.

Anti-cholinergic anti-Parkinsonian agents do not control tardive dyskinesia associated with long-term phenothiazine (or other anti-psychotic) therapy, and may exacerbate symptoms. Chlorpromazine is not effectively removed by haemodialysis.

SYMPTOMS AND TREATMENT OF OVERDOSE

Symptoms include hypotension, hypothermia, cardiac arrhythmias severe extrapyramidal symptoms, CNS depression and convulsion.

Treatment: Essentially symptomatic and supportive, induction of emesis is not advised as a dystonic reaction of head and neck may develop that could result in aspiration of vomitus. Early stomach lavage is often helpful. Administer activated charcoal slurry.

Administer saline cathartic.

Maintain respiratory function. Maintain body temperature.

Monitor cardiovascular function (not less than 5 days).

Control cardiac arrhythmias with neostigmine, pyridostigmine or propranolol. Digitalize for cardiac failure.

Administer vasopressor such as norepinephrine for hypotension. (Epinephrine should not be used as it may cause paradoxical

hypotension). Control convulsions with diazepam, paraldehyde or inhalation of anaesthetic. Control the acute pyramidal symptoms with benztropine or diphenhydramine. Severe CNS depression may require administration of a stimulant such as amphetamine, dextroamphetamine, or caffeine with sodium benzoate. (Picrotoxin or pentylentetrazol should be avoided). Dialysis of chlorpromazine has not been successful.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

The attention of patients, particularly drivers and machine operators, should be drawn to the risk of drowsiness with this medication especially at the start of treatment.

INSTRUCTIONS FOR USE

Method of administration: Oral

Dosages should be low to begin with and gradually increased under close supervision until the optimum dosage for the individual is reached. Individuals vary considerably and the optimum dose may be affected by the formulation used.

Dosage of chlorpromazine in schizophrenia, other psychoses, anxiety and agitation etc.:

Adult: Initially 25 mg t.d.s. or 75 mg at bedtime increasing by daily amounts of 25 mg to an effective maintenance dose. This is usually in the range 75 to 300 mg daily but some patients may require up to 1 g daily.

Children under 1 year: Do not use unless need is life-saving.

Children 1-5 years: 0.5 mg/kg body weight every 4-6 hours to a maximum recommended dose of 40 mg daily.

Children 6-12 years: 1/3-1/2 adult dose to a maximum recommended dose of 75 mg daily.

Elderly or debilitated patients: Start with 1/3-1/2 usual adult dose with a more gradual increase in dosage.

Hiccups:

Adult: 25-50 mg t.d.s. or q.d.s.

Children under 1 year: No information available.

Children 1-5 years: No information available.

Children 6-12 years: No information available.

Elderly or debilitated patients: As for adults.

Nausea and vomiting of terminal illness:

Adults: 10-25 mg every 4-6 hours.

Children under 1 year: Do not use unless need is life-saving.

Children 1-5 years: 0.5 mg/kg every 4-6 hours. Maximum daily dosage should not exceed 40 mg.

Children 6-12 years: 0.5 mg/kg every 4-6 hours. Maximum daily dosage should not exceed 75 mg.

Elderly or debilitated patients: Initially 1/3-1/2 adult dose. The physician should then use his clinical judgment to obtain control.

PACKING/PACK SIZES

Blister Pack of 10's - 50 Strips of 10 Tablets

STORAGE CONDITIONS

Store below 30°C, protect from light and moisture.

SHELF LIFE : Product should not be used beyond the expiry date imprinted on the product packaging.

REGISTRATION NO. : MAL19880027AZ

For further information, please consult your doctor or your pharmacist.

Revision Number : 07

Revision Date : 16 Jun 2026

Product Registration Holder and Manufacturer
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