Brand Name : CHLOZINE-25 TABLETS **Generic Name :** Chlorpromazine Tablets BP 25 mg	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

CHLOZINE-25 TABLETS (Chlorpromazine Tablets BP 25 mg)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains: Chlorpromazine Hydrochloride BP 25 mg

3. Pharmaceutical form:

White, circular, biconvex film coated tablets.

4. Clinical particulars:

4.1 Therapeutic Indications:

Chlorpromazine (**CPZ**), marketed under the brand names **Thorazine** and **Largactil** among others, is an antipsychotic medication. It is primarily used to treat psychotic disorders such as schizophrenia. Other uses include the treatment of bipolar disorder, severe behavioral problems in children including those with attention deficit hyperactivity disorder, nausea and vomiting, anxiety before surgery, and hiccups that do not improve following other measures. It can be given by mouth, by injection into a muscle, or into a vein.

Chlorpromazine is in the typical antipsychotic class, and, chemically, is one of the phenothiazines. Its mechanism of action is not entirely clear but believed to be related to its ability as a dopamine antagonist. It also has anti-serotonergic and antihistaminergic properties.

Common side effects include movement problems, sleepiness, dry mouth, low blood pressure upon standing, and increased weight. Serious side effects may include the potentially permanent movement disorder tardive dyskinesia, neuroleptic malignant syndrome, severe lowering of the seizure threshold, and low white blood cell levels. In older

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people with psychosis as a result of dementia it may increase the risk of death. It is unclear if it is safe for use in pregnancy.

Chlorpromazine was developed in 1950 and was the first antipsychotic. It is on the World Health Organization's List of Essential Medicines. Its introduction has been labeled as one of the great advances in the history of psychiatry. It is available as a generic medication

4.2 Posology and Method of Administration:

Adults

Adjust dosage to individual and the severity of his condition, recognizing that the milligram for milligram potency relationship among all dosage forms has not been precisely established clinically. It is important to increase dosage until symptoms are controlled. Dosage should be increased more gradually in debilitated or emaciated patients. In continued therapy, gradually reduce dosage to the lowest effective maintenance level, after symptoms have been controlled for a reasonable period.

Increase parenteral dosage only if hypotension has not occurred. Before using IM, see Important Notes On Injection.

ELDERLY PATIENTS

In general, dosages in the lower range are sufficient for most elderly patients. Since they appear to be more susceptible to hypotension and neuromuscular reactions, such patients should be observed closely. Dosage should be tailored to the individual, response carefully monitored, and dosage adjusted accordingly. Dosage should be increased more gradually in elderly patients.

PSYCHOTIC DISORDERS

Increase dosage gradually until symptoms are controlled. Maximum improvement may not be seen for weeks or even months. Continue optimum dosage for 2 weeks; then gradually reduce dosage to the lowest effective maintenance level. Daily dosage of 200 mg is not unusual. Some patients require higher dosages (e.g., 800 mg daily is not uncommon in discharged mental patients).

Hospitalized Patients: Acute Schizophrenic or Manic States

IM: 25 mg (1 mL). If necessary, give additional 25 to 50 mg injection in 1 hour. Increase subsequent IM doses gradually over several days–up to 400 mg q4-6h in exceptionally severe cases–until patient is controlled. Usually the patient becomes quiet and cooperative within 24 to 48 hours and oral doses may be substituted.

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Prompt Control of Severe Symptoms

IM: 25 mg (1 mL). If necessary, repeat in 1 hour. Subsequent doses should be oral, 25-50 mg tid.

NAUSEA AND VOMITING

IM: 25 mg (1 mL). If no hypotension occurs, give 25 to 50 mg q3-4h prn, until vomiting stops. Then switch to oral dosage.

During Surgery

IM: 12.5 mg (0.5 mL). Repeat in 1/2 hour if necessary and if no hypotension occurs. IV: 2 mg per fractional injection, at 2-minute intervals. Do not exceed 25 mg. Dilute to 1 mg/mL, i.e., 1 mL (25 mg) mixed with 24 mL of saline.

PRESURGICAL APPREHENSION

IM: 12.5 to 25 mg (0.5-1 mL), 1 to 2 hours before operation.

INTRACTABLE HICCUPS

If symptoms persist for 2-3 days after trial with oral therapy, give 25 to 50 mg (1-2 mL) IM. Should symptoms persist, use slow IV infusion with patient flat in bed: 25 to 50 mg (1-2 mL) in 500 to 1000 mL of saline. Follow blood pressure closely.

ACUTE INTERMITTENT PORPHYRIA

IM: 25 mg (1 mL) tid or qid until patient can take oral therapy.

TETANUS

IM: 25 to 50 mg (1-2 mL) given 3 or 4 times daily, usually in conjunction with barbiturates. Total doses and frequency of administration must be determined by the patient's response, starting with low doses and increasing gradually. IV: 25 to 50 mg (1-2 mL). Dilute to at least 1 mg per mL and administer at a rate of 1 mg per minute.

Pediatric Patients (6 months to 12 years of age)

Chlorpromazine should generally not be used in pediatric patients under 6 months of age except where potentially lifesaving. It should not be used in conditions for which specific pediatric dosages have not been established.

SEVERE BEHAVIORAL PROBLEMS

Outpatients

Select route of administration according to severity of patient's condition and increase dosage gradually as required. IM: 1/4 mg/lb body weight q6-8h, prn.

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Hospitalized Patients

As with outpatients, start with low doses and increase dosage gradually. In severe behavior disorders, higher dosages (50-100 mg daily, and in older children, 200 mg daily or more) may be necessary. There is little evidence that behavior improvement in severely disturbed mentally retarded patients is further enhanced by doses beyond 500 mg per day. Maximum IM Dosage: Patients up to 5 years (or 50 lbs.), not over 40 mg/day; 5-12 years (or 50-100 lbs.), not over 75 mg/day except in unmanageable cases.

NAUSEA AND VOMITING

Dosage and frequency of administration should be adjusted according to the severity of the symptoms and response of the patient. The duration of activity following intramuscular administration may last up to 12 hours. Subsequent doses may be given by the same route if necessary. IM: 1/4 mg/lb body weight q6-8h, prn. Maximum IM Dosage: Pediatric patients 6 months to 5 years (or 50 lbs.), not over 40 mg/day; 5-12 years (or 50-100 lbs.), not over 75 mg/day except in severe cases.

During Surgery

IM: 1/8 mg/lb body weight. Repeat in 1/2 hour if necessary and if no hypotension occurs. IV: 1 mg per fractional injection at 2-minute intervals and not exceeding recommended IM dosage. Always dilute to 1 mg/mL, i.e., 1 mL (25 mg) mixed with 24 mL of saline.

PRESURGICAL APPREHENSION

1/4 mg/lb body weight IM 1 to 2 hours before operation.

TETANUS

IM or IV: 1/4 mg/lb body weight q6-8h. When given IV, dilute to at least 1 mg/mL and administer at a rate of 1 mg per 2 minutes. In patients up to 50 lbs., do not exceed 40 mg daily; 50 to 100 lbs., do not exceed 75 mg except in severe cases.

Important Notes on Injection

Inject slowly, deep into upper outer quadrant of buttock.

Because of possible hypotensive effects, reserve parenteral administration for bedfast patients or for acute ambulatory cases, and keep patient lying down for at least 1/2 hour after injection. If irritation is a problem, dilute injection with saline or 2% procaine; mixing with other agents in the syringe is not recommended. Subcutaneous injection is not advised. AVOID INJECTING UNDILUTED CHLORPROMAZINE HYDROCHLORIDE INJECTION INTO VEIN. IV ROUTE IS ONLY FOR SEVERE HICCUPS, SURGERY AND TETANUS.

Because of the possibility of contact dermatitis, avoid getting solution on hands or clothing.

Method of administration: Oral.

4.3 Contraindications:

Absolute contraindications include:

- Circulatory
- CNS depression
- Coma
- Drug intoxication
- Bone marrow suppression
- Phaeochromocytoma
- Hepatic failure
- Active liver disease

- Previous hypersensitivity (including jaundice, agranulocytosis, etc.) to phenothiazines, especially chlorpromazine, or any of the excipients in the formulation being used.

Relative contraindications include:

- Epilepsy
- Parkinson's disease
- Myasthenia gravis
- Hypoparathyroidism
- Prostatic hypertrophy

Very rarely, elongation of the QT interval may occur, increasing the risk of potentially fatal arrhythmias.

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

5.2 Pharmacodynemic Properties:

Chlorpromazine is a psychotropic agent indicated for the treatment of schizophrenia. It also exerts sedative and antiemetic activity. Chlorpromazine has actions at all levels of the central nervous system-primarily at subcortical levels-as well as on multiple organ systems. Chlorpromazine has strong antiadrenergic and weaker peripheral anticholinergic activity; ganglionic blocking action is relatively slight. It also possesses slight antihistaminic and antiserotonin activity.

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6. Pharmaceutical particulars:

6.1 List of Excipients:

Di Basic Calcium Phosphate	BP
Maize starch	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Purified talc	BP
Magnesium stearate	BP
Colloidal silicon dioxide	BP
Cross Povidone	USP
Cross Carmellose Sodium	BP
Polacrillin Potassium	USP
Colour instacoat sol white 010	INH
Methylene dichloride	BP
Iso Propyl Alcohol	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
1000 tablets packed in one Jar.

6.6 Special precautions for disposal:
None reported.

7. Registrant:
AGOG PHARMA LTD.
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The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:
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9. Date of revision of the text :

AGOG Pharma Ltd.

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