1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

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INN (GENERIC NAME)
CHLORPROMAZINE TABLET BP 100 MG

1.2 Strength: - -- 100 mg

1.3 Pharmaceutical form: - Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
CHLORPROMAZINE TABLET BP 100 MG

Each film coated tablet contains:
Chlorpromazine Hydrochloride BP 100 mg
Excipients q.s.
Approved colour used.

Batch Size: 1, 05,000 Tablets

Sr. No.	Ingredients	Specification	Label amount mg	% Overages	Qty. / Tablet mg	Reason for Inclusion
1.	Chlorpromazine Hydrochloride	BP	100.00	--	100.00	Active
2.	Maize Starch*	BP		10 %	91.02	Diluent
3.	Lactose	BP		--	70.00	Diluent
4.	Microcrystalline Cellulose	BP		--	6.00	Diluent
5.	Sodium Starch Glycolate	BP		--	6.00	Disintegrant
6.	Maize Starch (For Paste)	BP		--	10.87	Binder
7.	Gelatin	BP		--	2.00	Binder
8.	Methyl Paraben	BP		--	0.10	Preservative
9.	Propyl Paraben	BP			0.01	Preservative
Lubricants						
10.	Purified Talc	BP		--	5.00	Lubricant
11.	Magnesium Stearate	BP		--	4.00	Lubricant
12.	Sodium Starch Glycolate	BP		--	5.00	Disintegrant

Film Coating

Sr. No.	Ingredients	Specification	Quantity/ Tablet (mg)	Reason for inclusion
13.	H.P.M.C.E 15CPS	BP	3.92	Film coat
14.	Titanium Dioxide	BP	1.71	Opacifier
15.	Purified Talc	BP	0.98	Filler
16.	Polyethylene Glycol 4000	BP	0.98	Plasticiser
17.	Propylene Glycol	BP	0.98	Humectant
18.	Methylene Chloride#	BP	--	Solvent
19.	Isopropyl Alcohol#	BP	--	Solvent

*10% extra quantity of Maize Starch taken to compensate the loss on drying.
#Not a part of finished product (Methylene Chloride & Isopropyl Alcohol evaporates during the manufacturing process)
We are applying total 2.86% solution for weight gaining 2.67% & 0.19% evaporation loss.
BP = British Pharmacopoeia
Average weight of Tablets = 308.0 mg ± 3 %

3. PHARMACEUTICAL FORM:

White coloured, elongated, biconvex, film coated tablets, having embossing “CHL 100” on one side & break line other side each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Schizophrenia and other psychoses (especially where paranoia is a predominant symptom), mania and hypomania. In anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behaviour. Chlorpromazine may be used as an adjunct in the short-term management of these conditions.
Intractable hiccup.
Nausea and vomiting in terminal illness (where other drugs have failed or are not available).
Induction of hypothermia is facilitated by Chlorpromazine Tablets which prevents shivering and causes vasodilatation.
Childhood schizophrenia and autism.

4.2 Posology and method of administration:

Posology
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 unlessthe risk-benefit ratio has been assessed.
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:
$^{1}/_{3}$-½ adult dose to a maximum recommended dose of 75 mg daily.
Elderly or debilitated patients:
Start with $^{1}/_{3}$-½ 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 unlessthe risk-benefit ratio has been assessed..
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 $^{1}/_{3}$-½ adult dose. The physician should then use his clinical judgment to obtain control.
Method of administration: Oral

4.3 Contraindications:
• Hypersensitivity to chlorpromazine or to any of the excipients
• Hypothyroidism
• Bone marrow depression
• Phaeochromocytoma
• Myasthenia gravis
• Risk of angle-closure glaucoma
• Risk of urinary retention related to urethroprostatic disorders
• History of agranulocytosis
• Dopaminergic antiparkinsonism agents
• Nursing mothers
• Citalopram, escitalopram

4.4 Special warnings and precautions for use:
Blood Dyscrasias: All patients must be advised that, if they experience fever, sore throat or any other infection, they should inform their physician immediately and undergo a complete blood count. Treatment will be discontinued if any marked changes (hyperleucocytosis, granulocytopenia) are observed in the latter.
As agranulocytosis has been reported, regular monitoring of the complete blood count is recommended. The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see Section 4.8) and requires immediate haematological investigation.
Neuroleptic malignant syndrome: treatment must be interrupted in the event of unexplained hyperpyrexia since this can be one of the signs of neuroleptic malignant syndrome (pallor, hyperthermia, disorders of autonomic function, altered consciousness, muscle rigidity). Signs of autonomic instability, such as hyperhydrosis and irregular blood pressure, can precede the onset of hyperthermia and as such constitute premonitory signs of the syndrome. While this neuroleptic-related effect can be of idiosyncratic origin, certain risk factors such as dehydration and brain damage would seem to indicate a predisposition.
Chlorpromazine should be avoided in patients with hypothyroidism, phaeochromocytoma, myasthenia gravis and prostate hypertrophy. It should be avoided in patients known to be

hypersensitive to phenothiazines or with a history of narrow angle glaucoma or agranulocytosis.
Acute withdrawal symptoms, including nausea, vomiting and insomnia, have very rarely have been reported following the abrupt cessation of high doses of neuroleptics. Relapse may also occur, and the emergence of extrapyramidal reactions has been reported. Therefore, gradual withdrawal is advisable.
In schizophrenia, the response to neuroleptic treatment may be delayed. If treatment is withdrawn, the recurrence of symptoms may not become apparent for some time.
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, hypokalaemia, 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
The concomitant use of chlorpromazine with lithium, other QT prolongation agents, and dopaminergic antiparkinsonism agents is not recommended.
The onset of paralytic ileus, potentially indicated by abdominal bloating and pain, must be treated as an emergency.
Cases of venous thromboembolism (VTE) sometimes fatal, have been reported with antipsychotic drugs. Since patients treated with anti-psychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Chlorpromazine and preventive measures undertaken.
Stroke: In randomised 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 patient cannot be excluded. Chlorpromazine should be used with caution in patients with stroke risk factors.
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 cause 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 patient is not clear.
As with all anti-psychotic drugs, Chlorpromazine should not be used alone where depression is predominant. However, it may be combined with antidepressant therapy to treat those conditions in which depression and psychosis coexist.
Chlorpromazine Tablets are not licensed for the treatment of dementia-related behavioural disturbances.

Because of the risk of photosensitisation, patients should be advised to avoid exposure to direct sunlight. In those frequently handling preparations of phenothiazines, the greatest care must be taken to avoid contact of the drug with the skin.
Hyperglycaemia or intolerance to glucose has been reported in patients treated with Chlorpromazine Tablets. Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes who are started on Chlorpromazine Tablets should get appropriate glycaemic monitoring during treatment.
• The following populations must be closely monitored after administration of chlorpromazine.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially, 'sodium free'

Paediatric population
Since there is a potential to impact on cognitive function, children should undergo a yearly clinical examination to evaluate learning capacity. The dosage should be adjusted regularly as a function of the clinical status of the child.

4.5 Interaction with other medicinal products and other forms of interaction:

Adrenaline must not be used in patients overdosed with Chlorpromazine.Antichlolinergic drugs may reduce the antipsychotic effect of Chlorpromazine and the mild anticholinergic effect of Chlorpromazine may be enhanced by other anticholinergic drugs possibly leading to constipation, heat stroke etc.

The action of some drugs may be opposed by Chlorpromazine; these include amphetamine, levodopa, clonidine, guanethidine and adrenaline.

Increases or decreases in the plasma concentrations of a number of drugs e.g. propranolol Phenobarbital have been observed but were not of clinical significance.

Simultaneous administration of deferoxamine and prochlorperazine has been observed to induce a transient metabolic encephalopathy characterised by loss of consciousness for 48-72 hours. It is possible this may occur with Chlorpromazine since it shares many of the pharmacological properties of prochlorperazine.

There is an increased risk of agranulocytosis when neuroleptics are used concurrently with drugs with myelosuppressive potential, such as carbamazepine or certain antibiotics and cytotoxics.

Combinations contraindicated

Dopaminergics (quinagolide, cabergoline), not including dopaminergic antiparkinsonism agents, are contraindicated: reciprocal antagonism of the dopaminergic agent and neuroleptic. Citalopram and escitalopram are contraindicated.

Combinations not recommended

Dopaminergic antiparkinsonism agents (amantadine, bromocriptine, cabergoline, levodopa, lisuride, pergolide, piribedil, ropinirole) are not recommended: reciprocal antagonism of the antiparkinsonism agent and neuroleptic. Neuroleptic-induced extrapyramidal syndrome should

be treated with an anticholinergic rather than a dopaminergic antiparkinsonism agent (dopaminergic receptors blocked by neuroleptics).

Levodopa: reciprocal antagonism of levodopa and the neuroleptic. In Parkinson's patients, it is recommended to use the minimal doses of each drug.

QT prolonging drugs: there is an increased risk of arrhythmias when chlorpromazine is used with concomitant QT prolonging drugs (including certain antiarrhythmics and other antipsychotics including sultopride) and drugs causing electrolyte imbalance .

Alcohol: alcohol potentiates the sedative effect of neuroleptics. Changes in alertness can make it dangerous to drive or operate machinery. Alcoholic beverages and medication containing alcohol should be avoided.

Lithium (high doses of neuroleptics): concomitant use can cause confusional syndrome, hypertonia and hyperreflexivity, occasionally with a rapid increase in serum concentrations of lithium. There have been rare cases of neurotoxicity Lithium can interfere with the absorption of neuroleptic agents.

Combinations requiring precautions

Antidiabetic agents: concomitant administration of high chlorpromazine doses (100 mg/day), and antidiabetic agents can lead to an increase in blood sugar levels (decreased insulin release). Forewarn the patient and advise increased self-monitoring of blood and urine levels. If necessary, adjust the antidiabetic dosage during and after discontinuing neuroleptic treatment.

Topical gastrointestinal agents (magnesium, aluminium and calcium salts, oxides and hydroxides): decreased GI absorption of phenothiazine neuroleptics. Do not administer phenothiazine neuroleptics simultaneously with topical GI agents (administer more than 2 hours apart if possible).

CYP1A2 inhibitors

Administration of chlorpromazine with CYP1A2 inhibitors, in particular strong or moderate inhibitors may lead to an increase of chlorpromazine plasma concentrations. Therefore, patients may experience a chlorpromazine dose-dependent adverse drug reaction.

There is a possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines and CYP2D6 substrates.

Combinations to be taken into consideration

Antihypertensive agents: potentiation of the antihypertensive effect and risk of orthostatic hypotension (additive effects). Guanethidine has adverse clinically significant interactions documented.

Atropine and other atropine derivatives: imipramine antidepressants, histamine H1-receptor antagonists, anticholinergic, antiparkinsonism agents, atropinic antispasmodics, disopyramide: build up of atropine-associated adverse effects such as urinary retention, constipation dry mouth and heat stroke etc.

Other CNS depressants: morphine derivatives (analgesics, antitussives and substitution treatments), barbiturates, benzodiazepines, anxiolytics other than benzodiazepines, hypnotics, sedative anti-depressants, histamine H1 receptor antagonists, central antihypertensive agents

increased central depression. Changes in alertness can make it dangerous to drive or operate machinery.

4.6 Pregnancy and lactation:

Pregnancy
There is inadequate evidence of the safety of chlorpromazine in human pregnancy. There is evidence of harmful effects in animals, so like other drugs, it should be avoided in pregnancy unless the physician considers it essential. It may occasionally prolong labour and at such a time should be withheld until the cervix is dilated 3-4cm. Possible adverse effects on the foetus include lethargy or paradoxical hyperexcitability, tremor and low Apgar score.
A large amount of exposure to chlorpromazine during pregnancy did not reveal any teratogenic effect.
It is advised to keep an adequate maternal psychic balance during pregnancy in order to avoid decompensation. If a treatment is necessary to ensure this balance, the treatment should be started or continued at effective dose all through the pregnancy.
Neonates exposed to antipsychotics (including chlorpromazine) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, bradycardia, tachycardia, feeding disorder, meconium ileus, delayed meconium passage, abdominal bloating. Consequently, newborns should be monitored carefully in order to plan appropriate treatment.

Breast-feeding
Chlorpromazine being excreted in milk, breast-feeding is not recommended during treatment.

Fertility
A decrease in fertility was observed in female animals treated with chlorpromazine. In male animals data are insufficient to assess fertility.
In humans, because of the interaction with dopamine receptors, chlorpromazine may cause hyperprolactinaemia which can be associated with impaired fertility in women. In men, data on consequences of hyperprolactinaemia are insufficient with regard to fertility.

4.7 Effects on ability to drive and use machines:

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.

4.8 Undesirable Effects:

The following undesired events, listed by body system, have been reported with the following frequencies: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1000 to <1/100), rare (≥ 1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

System organ class	Very common (≥ 1/10)	Common (≥ 1/100 to <1/10)	Not known (cannot be estimated from available data)
Blood and lymphatic system disorders			Agranulocytosis Leukopenia
Immune system disorders			Systemic lupus erythematosus Antinuclear antibody positive[1] Bronchospasm Anaphylactic reactions
Endocrine disorders		Hyperprolactinaemia Amenorrhoea	Galactorrhoea Gynaecomastia Erectile dysfunction Impotence Female sexual arousal disorder
Metabolism and nutrition disorders	Weight increased	Glucose tolerance impaired	Hyperglycaemia Hypertriglyceridaemia Hyponatraemia Inappropriate antidiuretic hormone secretion
Psychiatric disorders		Anxiety	Lethargy Mood altered
Nervous system disorders	Sedation[2] Somnolence[2] Dyskinesia (Acute dystonias or dyskenias, unusally transitory are more common in children and young adults and usually occur within the first 4 days of treatment or after dosage increases) Tardive dyskinesia[3] Extrapyramidal disorder Akathisia often after large initial dose	Hypertonia Convulsion	Torticollis Oculogyric crisis Trismus Akinesia Hyperkinesia Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) Parkinsonism (more common in adults and the elderly. It usually develops after weeks or months of treatment) to include tremor, rigidity or other features of Parkinsonism
Eye disorders			Accommodation disorder[4] Deposit eye[5] Ocular changes[7]

Cardiac disorders		ECG changes include Electrocardiogram QT Prolonged (as with other neuroleptics) , ST depression, U-Wave and T-Wave changes	Cardiac arrhythmias including Ventricular arrhythmia, a-v block, Ventricular fibrillation Ventricular tachycardia Torsade de pointes Cardiac arrest has been reported during neuroleptic phenothiazine therapy, possibly related to dosage. Pre-existing cardiac disease, old afe, hypokalaemia and concurrent tricyclic antidepressants may predispose. Sudden death/sudden cardiac death (with possible causes of cardiac origin as well as cases of unexplained sudden death, in patients receiving neuroleptic phenothiazines)
Vascular disorders	Orthostatic hypotension (Elderly or volume depleted subjects are particularly susceptible: it is more likely to occur after intramuscular administration).		Embolism venous Pulmonary embolism (sometimes fatal) Deep vein thrombosis
Respiratory, thoracic and mediastinal disorders			Respiratory depression Nasal stuffiness
Gastrointestinal disorders	Dry mouth Constipation		Colitis ischaemic Ileus paralytic Intestinal perforation (sometimes fatal) Gastrointestinal necrosis (sometimes fatal) Necrotising colitis (sometimes fatal) Intestinal obstruction
Hepatobiliary disorders			Jaundice cholestatic[6] Hepatocellular Liver injury[6] Cholestatic liver injury[6]

			Mixed liver injury
Skin and subcutaneous tissue disorders			Dermatitis allergic Angioedema Contact skin sensitisation may occur rarely in those frequently handling preparation of chlorpromazine Skin rashes Urticaria Photosensitivity reaction
Renal and urinary disorders			Urinary retention[4]
Pregnancy, puerperium and perinatal conditions			Drug withdrawal syndrome neonatal
Reproductive system and breast disorders			Priapism
General disorders and administration site conditions			Temperature regulation disorder Insomnia Agitation

4.9 OVERDOSE:

Toxicity and treatment of overdosage: Symptoms of chlorpromazine overdosage include drowsiness or loss of consciousness, hypotension, tachycardia, E.C.G. changes, ventricular arrhythmias and hypothermia, Parkinsonism, convulsions and coma. Severe extra-pyramidal dyskinesias may occur.

Treatment should be symptomatic with continuous respiratory and cardiac monitoring (risk of prolonged QT interval) until the patient's condition resolves.

If the patient is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose, gastric lavage may be attempted. Pharmacological induction of emesis is unlikely to be of any use. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

Generalised vasodilatation may result in circulatory collapse; raising the patient's legs may be sufficient in mild hypotension but, in severe cases, volume expansion by intravenous fluids may be needed; infusion fluids should be warmed before administration in order not to aggravate hypothermia.

Positive inotropic agents such as dopamine may be tried if fluid replacement is insufficient to correct the circulatory collapse. Peripheral vasoconstriction agents are not generally recommended; avoid use of adrenaline.

Ventricular or supraventricular tachy-arrhythmias usually respond to restoration of normal body temperature and correction of circulatory or metabolic disturbances. If persistent or life threatening, appropriate antiarrhythmic therapy may be considered. Avoid lidocaine and, as far as possible, long acting antiarrhythmic drugs.

Pronounced central nervous system depression requires airway maintenance or, in extreme circumstances, assisted respiration. Severe dystonic reactions usually respond to procyclidine (5-10 mg) or orphenedrine (20-40 mg) administered intramuscularly or intravenously. Convulsions should be treated with intravenous diazepam.

Neuroleptic malignant syndrome should be treated with cooling. Dantrolene sodium may be tried.

5 Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group: Antipsychotics, ATC Code: N05AA01. Chlorpromazine is a phenothiazine neuroleptic.
Chlorpromazine has depressant actions on the Central Nervous System, with alpha-adrenergic blocking and anticholinergic activities. It inhibits Dopamine and Prolactin release-inhibitory factor, thus stimulating the release of Prolactin. It increases the turnover of Dopamine in the brain.
It has anti-emetic, anti-pruritic, serotonin-blocking and weak anti-histamine properties and slight ganglion blocking activity. It inhibits the heat regulating centre in the brain, and is analgesic and can relax skeletal muscle.
Due to its action on the autonomic system, it produces vasodilatation, hypotension and tachycardia.
Salivary and gastric secretions are reduced.

5.2 Pharmacokinetic properties:

Chlorpromazine is rapidly absorbed and widely distributed in the body. It is metabolised in the liver and excreted in the urine and bile. Whilst plasma concentration of chlorpromazine itself rapidly declines excretion of chlorpromazine metabolites is very slow. The drug is highly bound to plasma protein. It readily diffuses across the placenta. Small quantities have been detected in milk from treated women. Children require smaller dosages per kg than adults.

5.3 Preclinical safety data:

Not applicable

6 Pharmaceutical Particulars

6.1 List of Excipients.

Sr. No.	Ingredients	Specifications
1.	Chlorpromazine Hydrochloride	BP 2024
2.	Maize Starch*	BP 2024
3.	Lactose	BP 2024
4.	Microcrystalline Cellulose	BP 2024
5.	Sodium Starch Glycolate	BP 2024
6.	Maize Starch (For Paste)	BP 2024
7.	Gelatin	BP 2024
8.	Methyl Paraben	BP 2024
9.	Propyl Paraben	BP 2024
10.	Purified Talc	BP 2024
11.	Magnesium Stearate	BP 2024
12.	Sodium Starch Glycolate	BP 2024
13.	Isopropyl Alcohol#	BP 2024
14.	Methylene Chloride#	BP 2024
15.	H.P.M.C.E 15CPS	BP 2024
16.	Titanium Dioxide	BP 2024
17.	Purified Talc	BP 2024
18.	Polyethylene Glycol 4000	BP 2024
19.	Propylene Glycol	BP 2024

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store in cool & dry place

6.5 Nature and contents of container

Jar pack of 1000 Tablets.

7 APPLICANT

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