Chlorpromazine Hydrochloride Tablets USP,
25 mg, 50 mg, 100 mg and 200 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	• For the management of manifestations of psychotic disorders. • For the treatment of schizophrenia. • To control nausea and vomiting. • For relief of restlessness and apprehension before surgery. • For acute intermittent porphyria. • As an adjunct in the treatment of tetanus. • To control the manifestations of the manic type of manic-depressive illness. • For relief of intractable hiccups. • For the treatment of severe behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance.

2	Dosage	What is the recommended dosage?	**DOSAGE AND ADMINISTRATION-ADULTS** **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 –** It is recommended that initial treatment be with chlorpromazine HCl injection until patient is controlled. Usually patient becomes quiet and co-operative within 24 to 48 hours and oral doses may be substituted and increased until the patient is calm. 500 mg a day is generally sufficient. While gradual increases to 2000 mg a day or more may be necessary, there is usually little therapeutic gain to be achieved by exceeding 1000 mg a day for extended periods. In general, dosage levels should be lower in the elderly, the emaciated and the debilitated. **Less Acutely Disturbed –** 25 mg t.i.d. Increase gradually until effective dose is reached – usually 400 mg daily. **Outpatients –** 10 mg t.i.d. or q.i.d., or 25 mg b.i.d. or t.i.d. More Severe Cases – 25 mg t.i.d. After 1 or 2 days, daily dosage may be increased by 20 to 50 mg at semi-weekly intervals until patient becomes calm and cooperative. **Prompt Control of Severe Symptoms –** Initial treatment should be with intramuscular chlorpromazine. Subsequent doses should be oral, 25 to 50 mg t.i.d. **Nausea and Vomiting –** 10 to 25 mg q4 to 6h, p.r.n., increased, if necessary. **Presurgical Apprehension –** 25 to 50 mg, 2 to 3 hours before the operation. **Intractable Hiccups –** 25 to 50 mg t.i.d. or q.i.d. If symptoms persist for 2 to 3 days, parenteral therapy is indicated. **Acute Intermittent Porphyria –** 25 to 50 mg t.i.d. or q.i.d. Can usually be discontinued. **DOSAGE AND ADMINISTRATION – 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. Oral: ¼ mg/lb body weight q4 to 6h, p.r.n. (e.g., for 40 lb child –10 mg q4 to 6h). **Hospitalized Patients –** As with outpatients, start with low doses and increase dosage gradually. In severe behavior disorders higher dosages (50 to 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 bydoses beyond 500 mg per day. **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. Oral: ¼ mg/lb body weight (e.g., 40lb child – 10 mg q4 to 6h). **Presurgical Apprehension –** ¼ mg/lb body weight orally 2 to 3 hours before operation.
3	Administration	Use in Pediatric Population	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. For dosage and administration in pediatric patients from 6 months to 12 years of age, please see above section or refer to full prescribing information.
	Administration	Use in Geriatric Population	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.
4	Mechanism	Mechanism of Action	The precise mechanism whereby the therapeutic effects of chlorpromazine are produced is not known. The principal pharmacological actions are psychotropic. 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
5	Warning	Black Box Warning	**Increased Mortality in Elderly Patients with Dementia-Related Psychosis** *See full prescribing information for complete details on Black Box Warning
6	Lactation	Use in Lactation	There is evidence that chlorpromazine is excreted in the breast milk of nursing mothers. Because of the potential for serious

			adverse reactions in nursing infants from chlorpromazine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
7	Pregnancy	Use in Pregnancy	Safety for the use of chlorpromazine during pregnancy has not been established. Therefore, it is not recommended that the drug be given to pregnant patients except when, in the judgment of the physician, it is essential. The potential benefits should clearly outweigh possible hazards. There are reported instances of prolonged jaundice, extrapyramidal signs, hyperreflexia or hyporeflexia in newborn infants whose mothers received phenothiazines
8	Storage	What are the storage conditions?	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature.] Protect from light and moisture
9	Dispensing	How to Dispense?	This package is not for household dispensing. If dispensed for outpatient use, a well closed, light-resistant, child-resistant container should be utilized.
10	Contraindication	What are the contraindications of (medication)?	Do not use in patients with known hypersensitivity to phenothiazines. Do not use in comatose states or in the presence of large amounts of central nervous system depressants (alcohol, barbiturates, narcotics, etc.).
Pharmaceutical Particulars			
11	Pharmaceutical Form	How Supplied	Chlorpromazine Hydrochloride Tablets, USP, 25 mg are available in bottles of 100 (NDC 72205-104-91). Chlorpromazine HCl Tablets, USP, 25 mg are light yellow to yellow colored, round shaped, biconvex, sugar coated tablets, imprinted "C2" with black ink on one side and plain on other side. Chlorpromazine Hydrochloride Tablets, USP, 50 mg are available in bottles of 100 (NDC 72205-105-91). Chlorpromazine HCl Tablets, USP, 50 mg are light yellow to yellow colored, round shaped, biconvex, sugar coated tablets, imprinted "C3" with black ink on one side and plain on other side. **THESE TABLET STRENGTHS LISTED BELOW ARE FOR USE ONLY IN SEVERE NEUROPSYCHIATRIC CONDITIONS**. Chlorpromazine Hydrochloride Tablets, USP, 100 mg are available in bottles of 100 (NDC 72205-106-91). Chlorpromazine HCl Tablets, USP, 100 mg are light yellow to yellow colored, round shaped, biconvex, sugar coated tablets, imprinted "C4" with black ink on one side and plain on other side. Chlorpromazine Hydrochloride Tablets, USP, 200 mg are available in bottles of 100 (NDC 72205-107-91). Chlorpromazine HCl Tablets, USP, 200 mg are light yellow to yellow colored, round shaped, biconvex, sugar coated tablets, imprinted "C5" with black in on one side and plain on other side. Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature.] Protect from light and moisture.

12	Ingredients	Active and Inactive	**Active ingredient:** Chlorpromazine hydrochloride **Inactive ingredients:** croscarmellose sodium, glyceryl monostreate, hypromellose, iron oxide yellow, iron oxide red, isopropyl alcohol, lactose monohydrate, magnesium sterate, medium chain triglycerides, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, precipitated calcium carbonate, sucrose, talc, titanium dioxide. The printing ink contains shellac, ferrosoferric oxide, propylene glycol.
Allergens			
13	Ingredients	Does it contain Gluten?	No
14	Ingredients	Does it contain alcohol?	Chlorpromazine API contais Iso propyl alcohol NMT 5000 PPM
15	Ingredients	Does it contain dyes?	Opadry colors Contains Dyes
16	Ingredients	Does it contain Lactose?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as an inactive ingredient.
17	Ingredients	Does it contain Nuts?	Opadry colors may contails
18	Ingredients	Does it contain Preservatives?	No
19	Ingredients	Does it contain Soy products?	No
20	Ingredients	Does it contain peanut?	No
21	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
22	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
23	Miscellaneous	May I know about return, refunds and reimbursement ?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
24	Miscellaneous	Do you have any patient's assistance program ?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
25	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products

26	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714