CENTER FOR DRUG EVALUATION AND RESEARCH

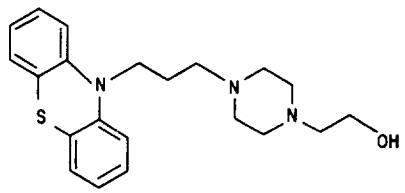
APPLICATION NUMBER:

40226

DRAFT FINAL PRINTED LABELING

Perphenazine Tablets, USP

DESCRIPTION Perphenazine tablets, USP contain perphenazine, USP (4-[3-(2-chlorophenothiazin-10-yl)propyl]-1-piperazineethanol), a piperazinyl phenothiazine having the molecular formula $C_{21}H_{26}ClN_3OS$. The structural formula is as follows:



$C_{21}H_{26}ClN_3OS$ MW = 403.98

Each tablet, for oral administration, contains perphenazine 2 mg, 4 mg, 8 mg., and 16 mg. In addition, each tablet contains the following inactive ingredients: acetone, black iron oxide, calcium carbonate, carnauba wax, eudragit, isobutyl alcohol, isopropyl alcohol, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze shellac, polyethyleneglycol, polyvinylpyrrolidone, povidone, sodium benzoate, sodium starch glycolate, sucrose, sucrose syrup, talc, titanium dioxide and water.

CLINICAL PHARMACOLOGY Perphenazine has actions at all levels of the central nervous system, particularly the hypothalamus. However, the site and mechanism of action of therapeutic effect are not known.

INDICATIONS AND USAGE Perphenazine tablets are indicated for use in the management of the manifestations of psychotic disorders; and for the control of severe nausea and vomiting in adults.

Perphenazine has not been shown effective in the management of behavioral complications in patients with mental retardation.

CONTRAINDICATIONS Perphenazine tablets are contraindicated in comatose or greatly obtunded patients and in patients receiving large doses of central nervous system depressants (barbiturates, alcohol, narcotics, analgesics, or antihistamines), in the presence of existing blood dyscrasias, bone marrow depression, or liver damage, and in patients who have shown hypersensitivity to perphenazine tablets, their components, or related compounds.

Perphenazine tablets are also contraindicated in patients with suspected or established subcortical brain damage, with or without hypothalamic damage, since a hyperthermic reaction with temperatures in excess of 104°F may occur in such patients, sometimes not until 14 to 16 hours after drug administration. Total body ice-packing is recommended for such a reaction; antipyretics may also be useful.

WARNINGS Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with neuroleptic (antipsychotic) drugs. Although the prevalence of the syndrome appears to be the highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of neuroleptic treatment, which patients are likely to develop the syndrome. Whether neuroleptic drug products differ in their potential to cause tardive dyskinesia is unknown.

Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of neuroleptic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if neuroleptic treatment is withdrawn. Neuroleptic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, and thereby may possibly mask the underlying disease process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, neuroleptics should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic neuroleptic treatment should generally be reserved for patients who suffer from a chronic illness that, 1) is known to respond to neuroleptic drugs, and, 2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do not require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on neuroleptics, drug discontinuation should be considered. However, some patients may require treatment despite the presence of the syndrome.

(For further information about the description of tardive dyskinesia and its clinical detection, please refer to **PRECAUTIONS, Information for Patients** and **ADVERSE REACTIONS.**)

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex, sometimes referred to as Neuroleptic Malignant Syndrome (NMS), has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrythmias).

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis it is important to identify cases where the clinical presentation includes both serious medical illness (e.g. pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system (CNS) pathology.

The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimes for uncomplicated NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

If hypotension develops, epinephrine should not be administered since its action is blocked and partially reversed by perphenazine. If a vasopressor is needed, norepinephrine may be used. Severe, acute hypotension has occurred with the use of phenothiazines and is particularly likely to occur in patients with mitral insufficiency or pheochromocytoma. Rebound hypertension may occur in pheochromocytoma patients.

Perphenazine tablets can lower the convulsive threshold in susceptible individuals: they should be used with caution in alcohol withdrawal and in patients with convulsive disorders. If the patient is being treated with an anticonvulsant agent, increased dosage of that agent may be required when perphenazine tablets are used concomitantly.

Perphenazine tablets should be used with caution in patients with psychic depression.

Perphenazine may impair the mental and/or physical abilities required for the performance of hazardous tasks such as driving a car or operating machinery, therefore, the patient should be warned accordingly.

Perphenazine tablets are not recommended for children under 12 years of age.

Usage in Pregnancy Safe use of perphenazine during pregnancy and lactation has not been established, therefore, in administering the drug to pregnant patients, nursing mothers, or women who may become pregnant, the possible benefits must be weighed against the possible hazards to mother and child.

PRECAUTIONS The possibility of suicide in depressed patients remains during treatment and until significant remission occurs. This type of patient should not have access to large quantities of this drug.

As with all phenothiazine compounds, perphenazine should not be used indiscriminately. Caution should be observed in giving it to patients who have previously exhibited severe adverse reactions to other phenothiazines. Some of the untoward actions of perphenazine tend to appear more frequently when high doses are used. However, as with other phenothiazine compounds, patients receiving perphenazine tablets in any dosage should be kept under close supervision.

Neuroleptic drugs elevate prolactin levels, the elevation persists during chronic administration. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent *in vitro*, a factor of potential importance if the prescription of these drugs is contemplated in a patient with a previously detected breast cancer. Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported, the clinical significance of elevated serum prolactin levels is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of neuroleptic drugs. Neither clinical studies nor epidemiologic studies conducted to date, however, have shown an association between chronic administration of these drugs and mammary tumorigenesis. The available evidence is considered too limited to be conclusive at this time.

The antiemetic effect of perphenazine may obscure signs of toxicity due to overdosage of other drugs, or render more difficult the diagnosis of disorders such as brain tumors or intestinal obstruction.

A significant, not otherwise explained, rise in body temperature may suggest individual intolerance to perphenazine, in which case it should be discontinued.

Patients on large doses of a phenothiazine drug who are undergoing surgery should be watched carefully for possible hypotensive phenomena. Moreover, reduced amounts of anesthetics or central nervous system depressants may be necessary.

Since phenothiazines and central nervous system depressants (opiates, analgesics, antihistamines, barbiturates) can potentiate each other, less than the usual dosage of the added drug is recommended and caution is advised when they are administered concomitantly.

Use with caution in patients who are receiving atropine or related drugs because of the additive anticholinergic effects and also in patients who will be exposed to extreme heat or phosphorus insecticides.

The use of alcohol should be avoided, since additive effects and hypotension may occur. Patients should be cautioned that their response to alcohol may be increased while they are being treated with perphenazine tablets. The risk of suicide and the danger of overdose may be increased in patients who use alcohol excessively due to its potentiation of the drug's effect.

Blood counts and hepatic and renal functions should be checked periodically. The appearance of signs of blood dyscrasias requires the discontinuance of the drug and institution of appropriate therapy. If abnormalities in hepatic tests occur, phenothiazine treatment with the drug should be discontinued. Renal function in patients on long-term therapy should be monitored; if blood urea nitrogen (BUN) becomes abnormal, treatment should be discontinued.

The use of phenothiazine derivatives in patients with diminished renal function should be undertaken with caution.

Use with caution in patients suffering from respiratory impairment due to acute pulmonary infections, or in chronic respiratory disorders such as severe asthma or emphysema.

In general, phenothiazines, including perphenazine, do not produce psychic dependence. Gastritis, nausea and vomiting, dizziness, and tremulousness have been reported following abrupt cessation of high-dose therapy. Reports suggest that these symptoms can be reduced by continuing concomitant antiparkinson agents for several weeks after the phenothiazine is withdrawn.

The possibility of liver damage, corneal and lenticular deposits, and irreversible dyskinesias should be kept in mind when patients are on long-term therapy.

Because photosensitivity has been reported, undue exposure to the sun should be avoided during phenothiazine treatment.

Information for Patients: This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Given the likelihood that a substantial proportion of patients exposed to neuroleptics will develop tardive dyskinesia, it is advised that all patients in whom chronic use is contemplated be given, if possible, full information about this risk. The decision to inform patients and/or their guardians must obviously take into account the clinical circumstances and the competency of the patient to understand the information provided.

ADVERSE REACTIONS Not all of the following adverse reactions have been reported with this specific drug; however, pharmacological similarities among various phenothiazine derivatives require that each be considered. With the piperazine group (of which perphenazine is an example), the extrapyramidal symptoms are more common, and others (e.g., sedative effects, jaundice, and blood dyscrasias) are less frequently seen.

CNS Effects: *Extrapyramidal reactions:* opisthotonus, trismus, torticollis, retrocollis, aching and numbness of the limbs, motor restlessness, oculogyric

crisis, hyperreflexia, dystonia, including protrusion, discoloration, aching and rounding of the tongue, tonic spasm of the masticatory muscles, tight feeling in the throat, slurred speech, dysphagia, akathisia, dyskinesia, parkinsonism, and ataxia. Their incidence and severity usually increase with an increase in dosage, but there is considerable individual variation in the tendency to develop such symptoms. Extrapyramidal symptoms can usually be controlled by the concomitant use of effective antiparkinsonian drugs, such as benztropine mesylate, and/or by reduction in dosage. In some instances, however, these extrapyramidal reactions may persist after discontinuation of treatment with perphenazine.

Persistive tardive dyskinesia: As with all antipsychotic agents, tardive dyskinesia may appear in some patients on long-term therapy or may appear after drug therapy has been discontinued. Although the risk appears to be greater in elderly patients on high-dose therapy, especially females, it may occur in either sex and in children. The symptoms are persistent and in some patients appear to be irreversible. The syndrome is characterized by rhythmical, involuntary movements of the tongue, face, mouth or jaw (e.g., protrusion of the tongue, puffing of the cheeks, puckering of mouth, chewing movements). Sometimes these may be accompanied by involuntary movements of the extremities. There is no known effective treatment for tardive dyskinesia; antiparkinsonism agents usually do not alleviate the symptoms of this syndrome. It is suggested that all antipsychotic agents be discontinued if these symptoms appear. Should it be necessary to reinstitute treatment, or increase the dosage of the agent, or switch to a different antipsychotic agent, the syndrome may be masked. It has been reported that fine, vermicular movements of the tongue may be an early sign of the syndrome, and if the medication is stopped at that time the syndrome may not develop.

Other CNS effects include cerebral edema; abnormality of cerebrospinal fluid proteins; convulsive seizures, particularly in patients with EEG abnormalities or a history of such disorders; and headaches.

Neuroleptic Malignant Syndrome (MNS) has been reported in patients treated with neuroleptic drugs (see **WARNINGS** section for further information).

Drowsiness may occur, particularly during the first or second week, after which it generally disappears. If troublesome, lower the dosage. Hypnotic effects appear to be minimal, especially in patients who are permitted to remain active.

Adverse behavioral effects include paradoxical exacerbation of psychotic symptoms, catatonic-like states, paranoid reactions, lethargy, paradoxical excitement, restlessness, hyperactivity, nocturnal confusion, bizarre dreams, and insomnia.

Hyperreflexia has been reported in the newborn when a phenothiazine was used during pregnancy.

Autonomic Effects: dry mouth or salivation, nausea, vomiting, diarrhea, anorexia, constipation, obstipation, fecal impaction, urinary retention, frequency or incontinence, bladder paralysis, polyuria, nasal congestion, pallor, myosis, mydriasis, blurred vision, glaucoma, perspiration, hypertension, hypotension, and change in pulse rate occasionally may occur. Significant autonomic effects have been infrequent in patients receiving less than 24 mg perphenazine daily.

Adynamic ileus occasionally occurs with phenothiazine therapy and if severe can result in complications and death. It is of particular concern in psychiatric patients, who may fail to seek treatment for the condition.

Allergic Effects: urticaria, erythema, eczema, exfoliative dermatitis, pruritus, photosensitivity, asthma, fever, anaphylactoid reactions, laryngeal edema, and angioneurotic edema; contact dermatitis in nursing personnel administering the drug; and in extremely rare instances, individual idiosyncrasy or hypersensitivity to phenothiazines has resulted in cerebral edema, circulatory collapse, and death.

Endocrine Effects: lactation, galactorrhea, moderate breast enlargement in females and gynecomastia in males on large doses, disturbances in the menstrual cycle, amenorrhea, changes in libido, inhibition of ejaculation, syndrome of inappropriate ADH (antidiuretic hormone) secretion, false positive pregnancy tests, hyperglycemia, hypoglycemia, glycosuria.

Cardiovascular Effects: postural hypotension, tachycardia (especially with sudden marked increase in dosage), bradycardia, cardiac arrest, faintness and dizziness. Occasionally the hypotensive effect may produce a shock-like condition. ECG changes, nonspecific (quinidine-like effect) usually reversible, have been observed in some patients receiving phenothiazine tranquilizers.

Sudden death has occasionally been reported in patients who have received phenothiazines. In some cases the death was apparently due to cardiac arrest; in others, the cause appeared to be asphyxia due to failure of the cough reflex. In some patients, the cause could not be determined nor could it be established that the death was due to the phenothiazine.

Hematological Effects: agranulocytosis, eosinophilia, leukopenia, hemolytic anemia, thrombocytopenic purpura and pancytopenia. Most cases of agranulocytosis have occurred between the fourth and tenth weeks of therapy. Patients should be watched closely, especially during that period, for the sudden appearance of sore throat or signs of infection. If the white blood cell and differential cell counts show significant cellular depression, discontinue the drug and start appropriate therapy. However, a slightly lowered white count is not in itself an indication to discontinue the drug.

Other Effects: Special considerations in long-term therapy include pigmentation of the skin, occurring chiefly in the exposed areas; ocular changes consisting of deposition of fine particulate matter in the cornea and lens, progressing in more severe cases to star-shaped lenticular opacities; epithelial keratopathies; and pigmentary retinopathy. Also noted: peripheral edema, reversed epinephrine effect, increase in PBI not attributable to an increase in thyroxine, parotid swelling (rare), hyperpyrexia, systemic lupus erythematosus-like syndrome, increases in appetite and weight, polyphagia, photophobia, and muscle weakness.

Liver damage (biliary stasis) may occur. Jaundice may occur, usually between the second and fourth weeks of treatment, and is regarded as a hypersensitivity reaction. Incidence is low. The clinical picture resembles infectious hepatitis but with laboratory features of obstructive jaundice. It is usually reversible, however, chronic jaundice has been reported.

OVERDOSAGE In the event of overdosage, emergency treatment should be started immediately. All patients suspected of having taken an overdose should be hospitalized as soon as possible.

Manifestations Overdosage of perphenazine primarily involves the extrapyramidal mechanism and produces the same side effects described under **ADVERSE REACTIONS**, but to a more marked degree. It is usually evidenced by stupor or coma, children may have convulsive seizures.

Treatment: Treatment is symptomatic and supportive. There is no specific antidote. The patient should be induced to vomit even if emesis has occurred spontaneously. Pharmacologic vomiting by the administration of ipecac syrup is a preferred method. It should be noted that ipecac has a central mode of action in addition to its local gastric irritant properties, and the central mode of action may be blocked by the antiemetic effect of perphenazine tablets. Vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of 8 to 12 fluid ounces of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in infants and children. Following emesis, any drug remaining in the stomach may be absorbed by activated charcoal administered as a slurry with water. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice. Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis and, therefore, may be valuable for their action in rapid dilution of bowel content.

Standard measures (oxygen, intravenous fluids, corticosteroids) should be used to manage circulatory shock and metabolic acidosis. An open airway and adequate fluid intake should be maintained. Body temperature should be regulated. Hypothermia is expected, but severe hyperthermia may occur and must be treated vigorously. (See **CONTRAINDICATIONS.**)

An electrocardiogram should be taken and close monitoring of cardiac function instituted if there is any sign of abnormality. Cardiac arrhythmias may be treated with neostigmine, pyridostigmine, or propranolol. Digitalis should be considered for cardiac failure. Close monitoring of cardiac function is advisable for not less than five days. Vasopressors such as norepinephrine may be used to treat hypotension, but epinephrine should NOT be used.

Anticonvulsants (an inhalation anesthetic, diazepam, or paraldehyde) are recommended for control of convulsions, since perphenazine increases the central nervous system depressant action, but not the anticonvulsant action of barbiturates.

If acute parkinson-like symptoms result from perphenazine intoxication, benztropine mesylate or diphenhydramine may be administered.

Central nervous system depression may be treated with nonconvulsant doses of CNS stimulants. Avoid stimulants that may cause convulsions (e.g., picrotoxin and pentylenetetrazol).

Signs of arousal may not occur for 48 hours.

Dialysis is of no value because of low plasma concentrations of the drug.

Since overdosage is often deliberate, patients may attempt suicide by other means during the recovery phase. Deaths by deliberate or accidental overdosage have occurred with this class of drugs.

DOSAGE AND ADMINISTRATION Dosage must be individualized and adjusted according to the severity of the condition and the response obtained. As with all potent drugs, the best dose is the lowest dose that will produce the desired clinical effect. Since extrapyramidal symptoms increase in frequency and severity with increased dosage, it is important to employ the lowest effective dose. These symptoms have disappeared upon reduction of dosage, withdrawal of the drug, or administration of an antiparkinsonian agent.

Prolonged administration of doses exceeding 24 mg daily should be reserved for hospitalized patients or patients under continued observation for early detection and management of adverse reactions. An antiparkinsonian agent, such as trihexyphenidyl hydrochloride or benztropine mesylate, is valuable in controlling drug-induced extrapyramidal symptoms.

Suggested dosages for various conditions follow:

Moderately disturbed nonhospitalized psychotic patients: **Tablets** 4 to 8 mg t.i.d initially; reduce as soon as possible to minimum effective dosage.

Hospitalized psychotic patients: **Tablets** 8 to 16 mg b.i.d. to q.i.d.; avoid dosages in excess of 64 mg daily.

Severe nausea and vomiting in adults: **Tablets** 8 to 16 mg daily in divided doses; 24 mg occasionally may be necessary, early dosage reduction is desirable.

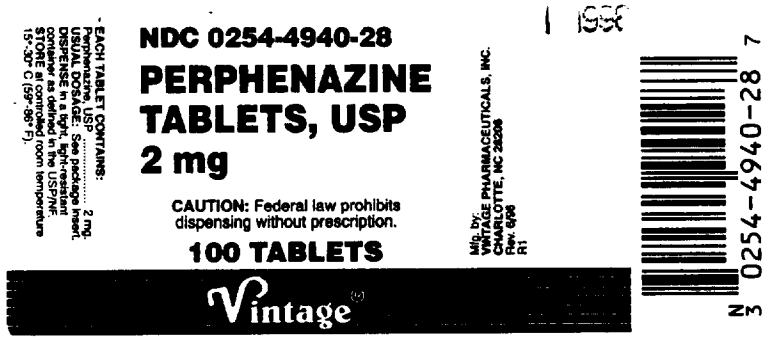
HOW SUPPLIED Perphenazine tablets, USP; gray, sugar-coated, unscored tablets branded in black with the following markings: 2 mg "4940 V", 4 mg "4941 V", 8 mg "4942 V", 16 mg "4943 V". Available in bottles of 100, 500 and 1000. Store at controlled room temperature 15°C–30°C (59°F–86°F).

Dispense in a tight, light-resistant container.

CAUTION: Federal law prohibits dispensing without a prescription.

Manufactured By:
Vintage Pharmaceuticals, Inc.
Charlotte, NC 28206

IN-134
Rev 7/97
R2


EACH TABLET CONTAINS:
Perphenazine, USP ..... 2 mg.
USUAL DOSAGE: See package insert.
DISPENSE in a tight, light-resistant container as defined in the USP/NF.
STORE at controlled room temperature 15°-30° C (59°-86° F).
NDC 0254-4940-28
PERPHENAZINE TABLETS, USP 2 mg
CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS
Vintage
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
R1
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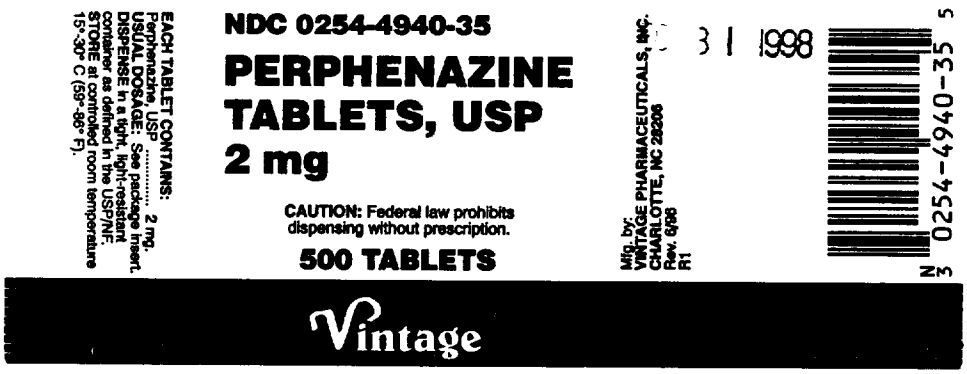
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NDC 0254-4940-35
PERPHENAZINE TABLETS, USP 2 mg
CAUTION: Federal law prohibits dispensing without prescription.
500 TABLETS
Vintage
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Rev. 6/98
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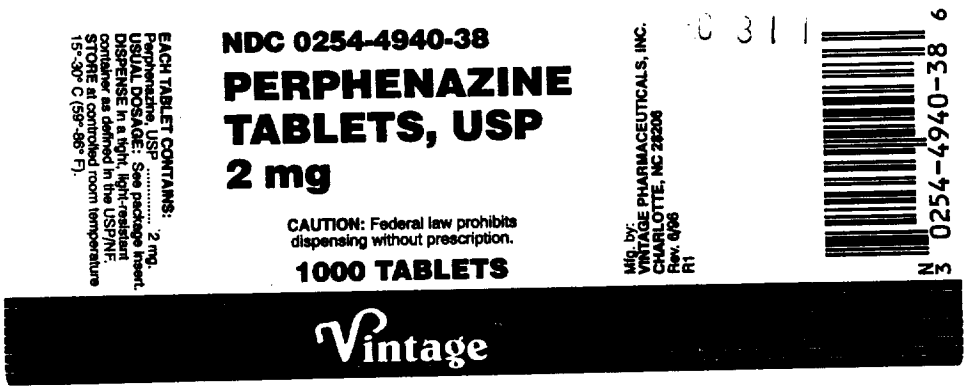
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NDC 0254-4940-38
PERPHENAZINE TABLETS, USP 2 mg
CAUTION: Federal law prohibits dispensing without prescription.
1000 TABLETS
Vintage
Mfg. by:
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CHARLOTTE, NC 28206
Rev. 6/98
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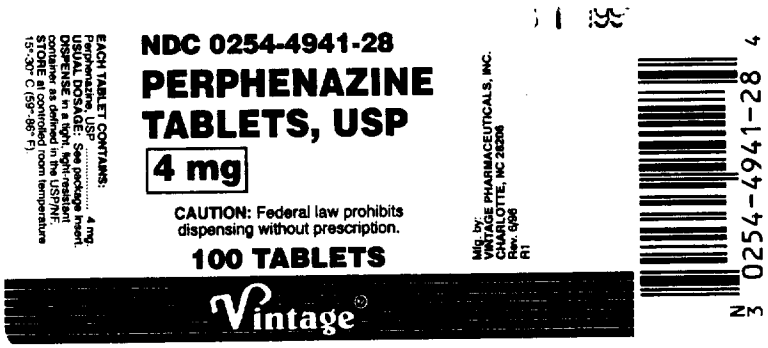
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Perphenazine, USP ..... 4 mg.
USUAL DOSAGE: See package insert.
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STORE at controlled room temperature 15°-30° C (59°-86° F).
NDC 0254-4941-28
PERPHENAZINE TABLETS, USP
4 mg
CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS
Vintage
Mfg. by:
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CHARLOTTE, NC 28206
Rev. 6/98
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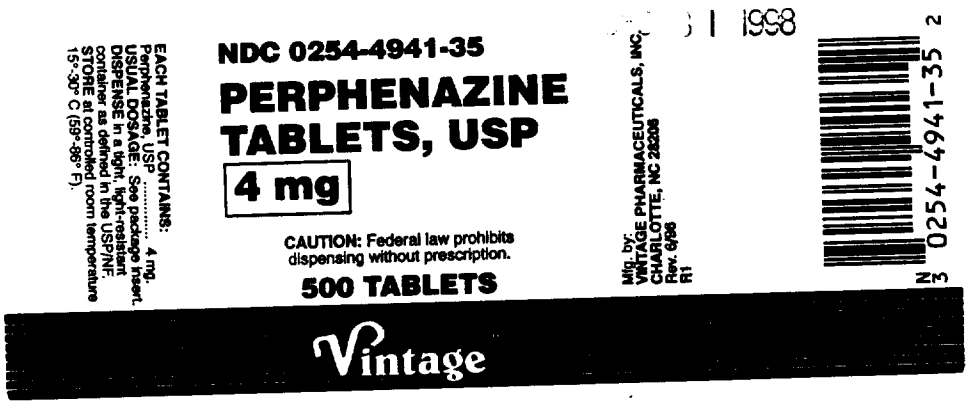
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NDC 0254-4941-35
PERPHENAZINE TABLETS, USP
4 mg
CAUTION: Federal law prohibits dispensing without prescription.
500 TABLETS
Vintage
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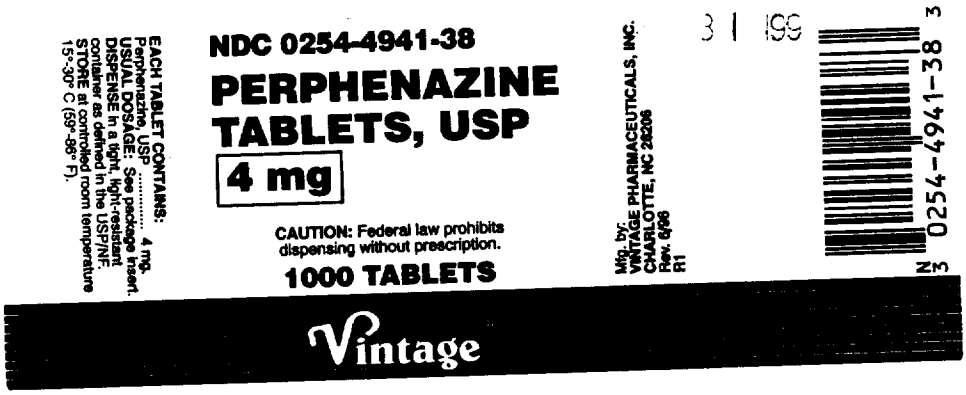
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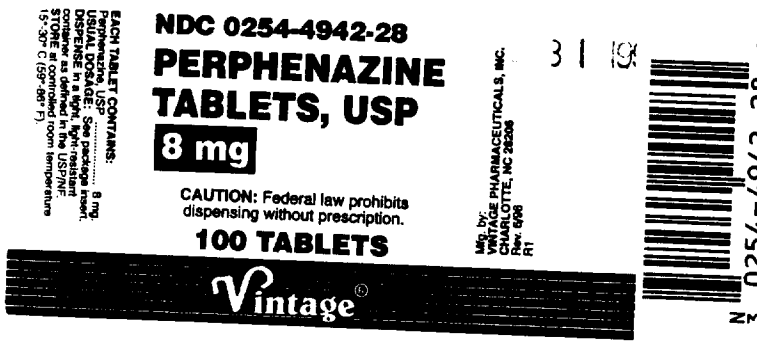
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USUAL DOSAGE: See package insert.
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NDC 0254-4942-28
PERPHENAZINE TABLETS, USP
8 mg
CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS
Vintage®
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
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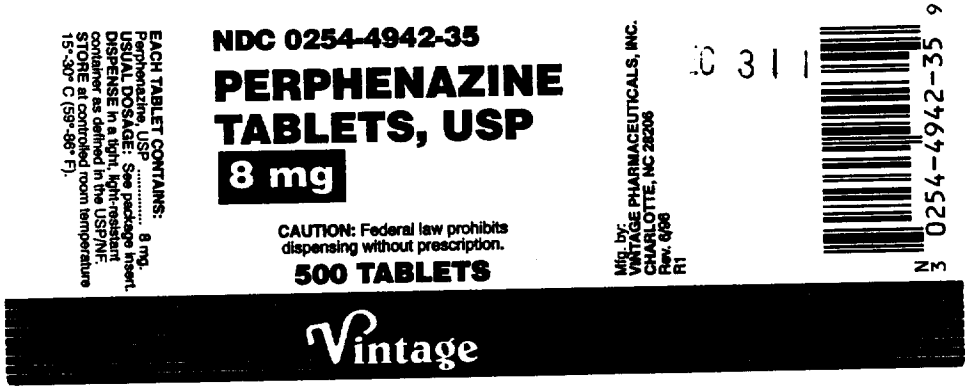
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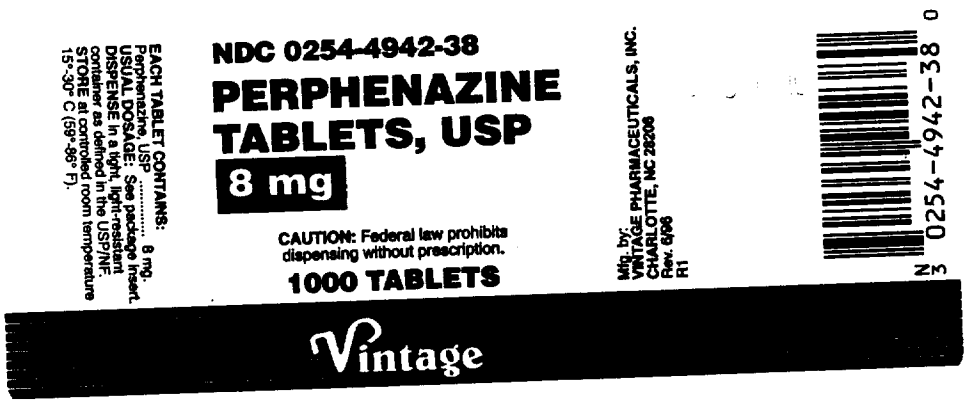
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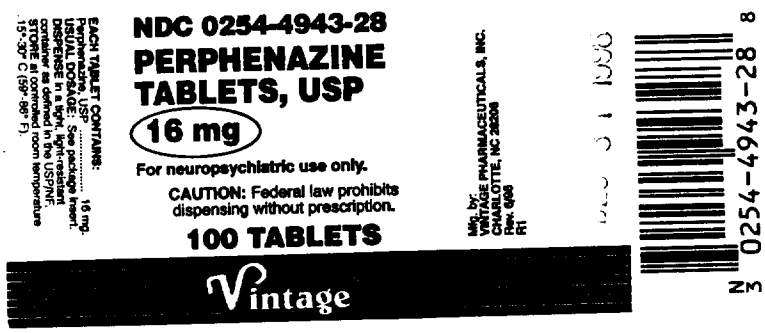
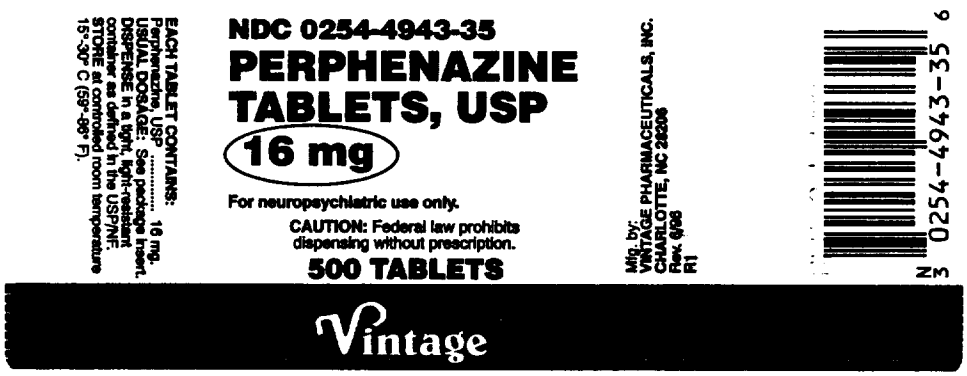
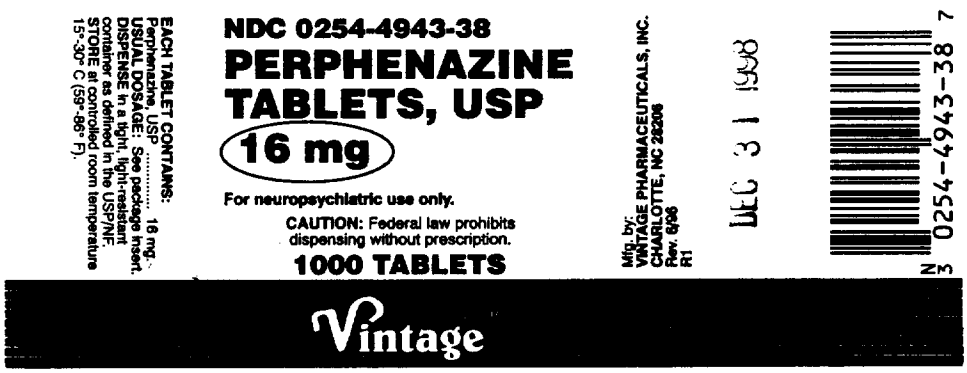
STORE at controlled room temperature 15°-30° C (59°-86° F).
NDC 0254-4942-38
PERPHENAZINE TABLETS, USP
8 mg
CAUTION: Federal law prohibits dispensing without prescription.
1000 TABLETS
Vintage
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
R1
N 3 0254-4942-38 0


NDC 0254-4943-28
PERPHENAZINE
TABLETS, USP
16 mg
For neuropsychiatric use only.
CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS
Vintage
EACH TABLET CONTAINS:
Perphenazine, USP ..... 16 mg.
USUAL DOSAGE: See package insert.
DISPENSE in a tight, light-resistant container as defined in the USP/NF.
STORE at controlled room temperature 15°-30° C (59°-86° F).
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
R1
DEC 31 1998
N 3 0254-4943-28 8


NDC 0254-4943-35
PERPHENAZINE
TABLETS, USP
16 mg
For neuropsychiatric use only.
CAUTION: Federal law prohibits dispensing without prescription.
500 TABLETS
Vintage
EACH TABLET CONTAINS:
Perphenazine, USP ..... 16 mg.
USUAL DOSAGE: See package insert.
DISPENSE in a tight, light-resistant container as defined in the USP/NF.
STORE at controlled room temperature 15°-30° C (59°-86° F).
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
R1
N 3 0254-4943-35 6


NDC 0254-4943-38
PERPHENAZINE
TABLETS, USP
16 mg
For neuropsychiatric use only.
CAUTION: Federal law prohibits dispensing without prescription.
1000 TABLETS
Vintage
EACH TABLET CONTAINS:
Perphenazine, USP ..... 16 mg.
USUAL DOSAGE: See package insert.
DISPENSE in a tight, light-resistant container as defined in the USP/NF.
STORE at controlled room temperature 15°-30° C (59°-86° F).
Mfg. by:
VINTAGE PHARMACEUTICALS, INC.
CHARLOTTE, NC 28206
Rev. 6/98
R1
DEC 31 1998
N 3 0254-4943-38 7