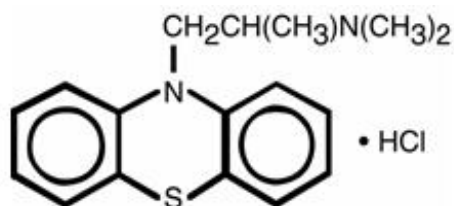


**PROMETHAZINE HCL- promethazine hydrochloride injection**  
**Watson Laboratories, Inc.**

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**PROMETHAZINE HCl INJECTION USP**  
**Rx Only**

**DESCRIPTION**

Promethazine HCl Injection USP is a sterile, pyrogen-free solution for deep intramuscular or intravenous administration. Promethazine HCl (10*H*-phenothiazine-10-ethanamine, *N,N*, $\alpha$ -trimethyl-, monohydrochloride, ( $\pm$ )-) is a racemic compound and has the following structural formula:



**C<sub>17</sub>H<sub>21</sub>ClN<sub>2</sub>S** MW = 320.89

Each mL contains: Promethazine HCl 25 mg or 50 mg, Edetate Disodium 0.1 mg, Calcium Chloride 0.04 mg, Sodium Metabisulfite 0.25 mg, with Phenol 5 mg as preservative, in Water for Injection, q.s. Buffered with Glacial Acetic Acid and Sodium Acetate, Trihydrate. The pH range is 4.0 to 5.5. Sealed under Nitrogen.

Promethazine HCl Injection is a clear, colorless solution. The product is light sensitive. It should be inspected before use and discarded if either color or particulate is observed.

**CLINICAL PHARMACOLOGY**

Promethazine HCl is a phenothiazine derivative which possesses antihistaminic, sedative, antiemetic, and anticholinergic effects. Promethazine is a competitive H<sub>1</sub> receptor antagonist, but does not block the release of histamine. Structural differences from the neuroleptic phenothiazines results in its relative lack (1/10) of dopamine antagonist properties. In therapeutic doses, promethazine HCl produces no significant effects on the cardiovascular system. Clinical effects are generally apparent within 5 minutes of an intravenous injection and within 20 minutes of an intramuscular injection. Duration of action is four to six hours, although effects may persist up to 12 hours. Promethazine HCl is metabolized in the liver, with the sulfoxides of promethazine and *N*-desmethylpromethazine being the predominant metabolites appearing in the urine. Following intravenous administration in healthy volunteers, the plasma half-life for promethazine has been reported to range from 9 to 16 hours. The mean plasma half-life for promethazine after intramuscular administration in healthy volunteers has been reported to be 9.8 $\pm$ 3.4 hours.

**INDICATIONS AND USAGE**

Promethazine HCl Injection is indicated for the following conditions:

1. Amelioration of allergic reactions to blood or plasma.
2. In anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled.
3. For other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.

4. For sedation and relief of apprehension and to produce light sleep from which the patient can be easily aroused.
5. Active treatment of motion sickness.
6. Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery.
7. As an adjunct to analgesics for the control of postoperative pain.
8. Preoperative, postoperative, and obstetric (during labor) sedation.
9. Intravenously in special surgical situations, such as repeated bronchoscopy, ophthalmic surgery, and poor-risk patients, with reduced amounts of meperidine or other narcotic analgesic as an adjunct to anesthesia and analgesia.

## CONTRAINDICATIONS

Promethazine HCl Injection is contraindicated in comatose states and in patients who have demonstrated an idiosyncrasy or hypersensitivity to promethazine or other phenothiazines.

Under no circumstances should Promethazine HCl Injection be given by intra-arterial injection due to the likelihood of severe arteriospasm and the possibility of resultant gangrene (see "WARNINGS - Inadvertent Intra-arterial Injection").

Promethazine HCl Injection should not be given by the subcutaneous route; evidence of chemical irritation has been noted, and necrotic lesions have resulted on rare occasions following subcutaneous injection. The preferred parenteral route of administration is by deep intramuscular injection.

## WARNINGS

### BOXED WARNING

**PROMETHAZINE HCl SHOULD NOT BE USED IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE BECAUSE OF THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION.**

**POSTMARKETING CASES OF RESPIRATORY DEPRESSION, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH USE OF PROMETHAZINE HCl IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE. A WIDE RANGE OF WEIGHT-BASED DOSES OF PROMETHAZINE HCl HAVE RESULTED IN RESPIRATORY DEPRESSION IN THESE PATIENTS.**

**CAUTION SHOULD BE EXERCISED WHEN ADMINISTERING PROMETHAZINE HCl TO PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER. IT IS RECOMMENDED THAT THE LOWEST EFFECTIVE DOSE OF PROMETHAZINE HCl BE USED IN PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER AND CONCOMITANT ADMINISTRATION OF OTHER DRUGS WITH RESPIRATORY DEPRESSANT EFFECTS BE AVOIDED.**

### Sulfite Sensitivity

Promethazine HCl Injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthma episodes, in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

### CNS Depression

Promethazine HCl Injection may impair the mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. The impairment may be amplified by concomitant use of other central nervous system depressants such as alcohol, sedative-hypnotics (including barbiturates), general anesthetics, narcotics, narcotic analgesics, tranquilizers, etc. (see "PRECAUTIONS - Information for Patients").

### **Lower Seizure Threshold**

Promethazine HCl Injection may lower seizure threshold and should be used with caution in persons with seizure disorders or in persons who are using concomitant medications, such as narcotics or local anesthetics, which may also affect seizure threshold.

### **Bone Marrow Depression**

Promethazine HCl Injection should be used with caution in patients with bone marrow depression. Leukopenia and agranulocytosis have been reported, usually when promethazine HCl has been used in association with other known marrow-toxic agents.

### **Use in Pediatric Patients**

**PROMETHAZINE HCl INJECTION IS CONTRAINDICATED FOR USE IN PEDIATRIC PATIENTS LESS THAN TWO YEARS OF AGE.**

**CAUTION SHOULD BE EXERCISED WHEN ADMINISTERING PROMETHAZINE HCl INJECTION TO PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER BECAUSE OF THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION. RESPIRATORY DEPRESSION AND APNEA, SOMETIMES ASSOCIATED WITH DEATH, ARE STRONGLY ASSOCIATED WITH PROMETHAZINE PRODUCTS AND NOT FIRMLY WEIGHT-RELATED, WHICH MIGHT OTHERWISE PERMIT SAFE ADMINISTRATION OF INDIVIDUALIZED DOSING. CONCOMITANT ADMINISTRATION OF PROMETHAZINE PRODUCTS WITH OTHER RESPIRATORY DEPRESSANTS HAS AN ASSOCIATION WITH RESPIRATORY DEPRESSION, AND SOMETIMES DEATH, IN PEDIATRIC PATIENTS.**

**ANTIEMETICS ARE NOT RECOMMENDED FOR TREATMENT OF UNCOMPLICATED VOMITING IN PEDIATRIC PATIENTS, AND THEIR USE SHOULD BE LIMITED TO PROLONGED VOMITING OF KNOWN ETIOLOGY. THE EXTRAPYRAMIDAL SYMPTOMS WHICH CAN OCCUR SECONDARY TO PROMETHAZINE HCl INJECTION ADMINISTRATION MAY BE CONFUSED WITH THE CNS SIGNS OF UNDIAGNOSED PRIMARY DISEASE, e.g., ENCEPHALOPATHY OR REYE'S SYNDROME. THE USE OF PROMETHAZINE HCl INJECTION SHOULD BE AVOIDED IN PEDIATRIC PATIENTS WHOSE SIGNS AND SYMPTOMS MAY SUGGEST REYE'S SYNDROME OR OTHER HEPATIC DISEASES.**

Excessively large dosages of antihistamines, including Promethazine HCl Injection, in pediatric patients may cause hallucinations, convulsions, and sudden death. In pediatric patients who are acutely ill associated with dehydration, there is an increased susceptibility to dystonias with the use of Promethazine HCl Injection.

### **Inadvertent Intra-arterial Injection**

Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Promethazine HCl Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but

perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs, although sympathetic block and heparinization are commonly employed during the acute management because of the results of animal experiments with other known arteriolar irritants. Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with Promethazine HCl Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone.

When used intravenously, Promethazine HCl Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily. In the event that a patient complains of pain during intended intravenous injection of Promethazine HCl Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.

### **Visual Inspection**

This product is light sensitive and should be inspected before use and discarded if either color or particulate is observed.

### **Other Considerations**

Sedative drugs or CNS depressants should be avoided in patients with a history of sleep apnea. Administration of promethazine has been associated with reported cholestatic jaundice.

## **PRECAUTIONS**

### **General**

Drugs having anticholinergic properties should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, and bladder-neck obstruction.

Promethazine HCl Injection should be used cautiously in persons with cardiovascular disease or impairment of liver function.

### **Information for Patients**

Promethazine HCl Injection may cause marked drowsiness or impair the mental or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. The use of alcohol, sedative-hypnotics (including barbiturates), general anesthetics, narcotics, narcotic analgesics, tranquilizers, etc. with Promethazine HCl Injection may enhance impairment. Pediatric patients should be supervised to avoid potential harm in bike riding or in other hazardous activities.

Patients should be advised to report any involuntary muscle movements.

Persistent or worsening pain or burning at the injection site should be reported immediately.

Avoid prolonged exposure to the sun.

### **Drug Interactions**

#### **CNS Depressants -**

Promethazine HCl Injection may increase, prolong, or intensify the sedative action of central nervous system depressants, such as alcohol, sedative-hypnotics (including barbiturates), general anesthetics, narcotics, narcotic analgesics, tranquilizers, etc. When given concomitantly with Promethazine HCl Injection, the dose of barbiturates should be reduced by at least one-half, and the dose of narcotics should be reduced by one-quarter to one-half. Dosage must be individualized. Excessive amounts of

Promethazine HCl Injection relative to a narcotic may lead to restlessness and motor hyperactivity in the patient with pain; these symptoms usually disappear with adequate control of the pain.

Epinephrine -

Although reversal of the vasopressor effect of epinephrine has not been reported with Promethazine HCl Injection, it is recommended that epinephrine NOT be used in the case of Promethazine HCl Injection overdose.

Anticholinergics -

Concomitant use of other agents with anticholinergic properties should be undertaken with caution.

Monoamine Oxidase Inhibitors (MAOI) -

Drug interactions, including an increased incidence of extrapyramidal effects, have been reported when some MAOI and phenothiazines are used concomitantly. Although such a reaction has not been reported with Promethazine HCl Injection, the possibility should be considered.

### **Laboratory Tests Interactions**

The following laboratory tests may be affected in patients who are receiving therapy with Promethazine HCl Injection:

Pregnancy Tests -

Diagnostic pregnancy tests based on immunological reactions between HCG and anti-HCG may result in false-negative or false-positive interpretations.

Glucose Tolerance Test -

An increase in glucose tolerance has been reported in patients receiving promethazine HCl.

### **Carcinogenesis, Mutagenesis, and Impairment of Fertility**

Long term animal studies have not been performed to assess the carcinogenic potential of Promethazine HCl Injection, nor are there other animal or human data concerning carcinogenicity, mutagenicity, or impairment of fertility. Promethazine HCl Injection was nonmutagenic in the Ames *Salmonella* test system.

### **Pregnancy**

Teratogenic Effects – Pregnancy Category C:

Teratogenic effects have not been demonstrated in rat feeding studies at doses of 6.25 and 12.5 mg/kg (approximately 2.1 and 4.2 times the maximum recommended human daily dose) of Promethazine HCl Injection. Daily doses of 25 mg/kg intraperitoneally have been found to produce fetal mortality in rats.

There are no adequate and well-controlled studies of Promethazine HCl Injection in pregnant women. Because animal reproduction studies are not always predictive of human response, Promethazine HCl Injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adequate studies to determine the action of the drug on parturition, lactation and development of the animal neonate have not been conducted.

Nonteratogenic Effects

Promethazine HCl Injection received within two weeks of delivery may inhibit platelet aggregation in the newborn.

### **Labor and Delivery**

Promethazine HCl Injection may be used alone or as an adjunct to narcotic analgesics during labor (see “DOSAGE AND ADMINISTRATION”). Limited data suggest that use of Promethazine HCl Injection

during labor and delivery does not have an appreciable effect on the duration of labor or delivery and does not increase the risk of need for intervention in the newborn. The effect on later growth and development of the newborn is unknown. (See also “Pregnancy: Nonteratogenic Effects.”)

### **Nursing Mothers**

It is not known whether Promethazine HCl Injection is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Promethazine HCl Injection is administered to a nursing woman.

### **Pediatric Use**

Safety and effectiveness in pediatric patients under 2 years of age have not been established.

Promethazine HCl Injection should be used with caution in pediatric patients 2 years of age and older (see “WARNINGS - Use in Pediatric Patients”).

### **Use in Geriatric Patients (Approximately 60 Years or Older)**

Since therapeutic requirements for sedative drugs tend to be less in geriatric patients, the dosage should be reduced for these patients.

## **ADVERSE REACTIONS**

### **CNS Effects:**

Drowsiness is the most prominent CNS effect of this drug. Extrapramidal reactions may occur with high doses; this is almost always responsive to a reduction in dosage. Other reported reactions include dizziness, lassitude, tinnitus, incoordination, fatigue, blurred vision, euphoria, diplopia, nervousness, insomnia, tremors, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, and hallucinations.

### **Cardiovascular Effects:**

Tachycardia, bradycardia, faintness, dizziness, and increases and decreases in blood pressure have been reported following the use of Promethazine HCl Injection. Venous thrombosis at the injection site has been reported. INTRA-ARTERIAL INJECTION MAY RESULT IN GANGRENE OF THE AFFECTED EXTREMITY (see “WARNINGS - Inadvertent Intra-arterial Injection”).

### **Gastrointestinal Effects:**

Nausea and vomiting have been reported, usually in association with surgical procedures and combination drug therapy.

### **Allergic Reactions:**

These include urticaria, dermatitis, asthma, and photosensitivity. Angioneurotic edema has been reported.

### **Other Reported Reactions:**

Leukopenia and agranulocytosis, usually when promethazine HCl has been used in association with other known marrow-toxic agents, have been reported. Thrombocytopenic purpura and jaundice of the obstructive type have been associated with the use of promethazine HCl. The jaundice is usually reversible on discontinuation of the drug. Subcutaneous injection has resulted in tissue necrosis. Nasal stuffiness may occur. Dry mouth has been reported.

### **Paradoxical Reactions (Overdosage):**

Hyperexcitability and abnormal movements, which have been reported in pediatric patients following a single administration of Promethazine HCl Injection, may be manifestations of relative overdose, in which case, consideration should be given to the discontinuation of Promethazine HCl Injection and to the use of other drugs. Respiratory depression, nightmares, delirium, and agitated behavior have also been reported in some of these patients.

## **OVERDOSAGE**

Signs and symptoms of overdose range from mild depression of the central nervous system and cardiovascular system to profound hypotension, respiratory depression, and unconsciousness.

Stimulation may be evident, especially in pediatric patients and geriatric patients. Convulsions may rarely occur. A paradoxical reaction has been reported in pediatric patients receiving single doses of 75 mg to 125 mg orally, characterized by hyperexcitability and nightmares.

Atropine-like signs and symptoms - dry mouth; fixed, dilated pupils; flushing; etc., as well as gastrointestinal symptoms, may occur.

### **Treatment:**

Treatment of overdose is essentially symptomatic and supportive. Only in cases of extreme overdose or individual sensitivity do vital signs, including respiration, pulse, blood pressure, temperature, and EKG, need to be monitored. Attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. Diazepam may be used to control convulsions. Acidosis and electrolyte losses should be corrected. Note that any depressant effects of Promethazine HCl Injection are not reversed by naloxone.

Avoid analeptics, which may cause convulsions. The treatment of choice for resulting hypotension is administration of intravenous fluids, accompanied by repositioning if indicated. In the event that vasopressors are considered for the management of severe hypotension which does not respond to intravenous fluids and repositioning, the administration of levarterenol or phenylephrine should be considered. EPINEPHRINE SHOULD NOT BE USED, since its use in a patient with partial adrenergic blockade may further lower the blood pressure. Extrapyrarnidal reactions may be treated with anticholinergic antiparkinson agents, diphenhydramine, or barbiturates. Oxygen may also be administered. Limited experience with dialysis indicates that it is not helpful.

## **DOSAGE AND ADMINISTRATION**

**Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.**

Do not use Promethazine HCl Injection if solution has developed color or contains precipitate.

To avoid the possibility of physical and/or chemical incompatibility, consult specialized literature before diluting with any injectable solution or combining with any other medication. Do not use if there is a precipitate or any sign of incompatibility.

**Important Notes on Administration:** The preferred parenteral route of administration for Promethazine HCl Injection is by deep intramuscular injection. The proper intravenous administration of this product is well-tolerated, but use of this route is not without some hazard. Not for subcutaneous administration.

**INADVERTENT INTRA-ARTERIAL INJECTION CAN RESULT IN GANGRENE OF THE AFFECTED EXTREMITY** (see "WARNINGS - Inadvertent Intra-arterial Injection").  
**SUBCUTANEOUS INJECTION IS CONTRAINDICATED, AS IT MAY RESULT IN TISSUE NECROSIS** (see "CONTRAINDICATIONS").

Injection into or near a nerve may result in permanent tissue damage.

When used intravenously, Promethazine HCl Injection should be given in a concentration no greater than 25 mg/mL at a rate not to exceed 25 mg per minute; it is preferable to inject through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.

**Allergic Conditions:**

The average adult dose is 25 mg. This dose may be repeated within two hours if necessary, but continued therapy, if indicated, should be via the oral route as soon as existing circumstances permit. After initiation of treatment, dosage should be adjusted to the smallest amount adequate to relieve symptoms. The average adult dose for amelioration of allergic reactions to blood or plasma is 25 mg.

**Sedation:**

In hospitalized adult patients, nighttime sedation may be achieved by a dose of 25 to 50 mg of Promethazine HCl Injection.

**Nausea and Vomiting:**

For control of nausea and vomiting, the usual adult dose is 12.5 to 25 mg, not to be repeated more frequently than every four hours. When used for control of postoperative nausea and vomiting, the medication may be administered either intramuscularly or intravenously and dosage of analgesics and barbiturates reduced accordingly.

**Preoperative and Postoperative Use:**

As an adjunct to preoperative or postoperative medication, 25 to 50 mg of Promethazine HCl Injection in adults may be combined with appropriately reduced doses of analgesics and atropine-like drugs as desired. Dosage of concomitant analgesic or hypnotic medication should be reduced accordingly.

**Obstetrics:**

Promethazine HCl Injection in doses of 50 mg will provide sedation and relieve apprehension in the early stages of labor. When labor is definitely established, 25 to 75 mg (average dose, 50 mg) Promethazine HCl Injection may be given intramuscularly or intravenously with an appropriately reduced dose of any desired narcotic. If necessary, Promethazine HCl Injection with a reduced dose of analgesic may be repeated once or twice at four-hour intervals in the course of a normal labor. A maximum total dose of 100 mg of Promethazine HCl Injection may be administered during a 24-hour period to patients in labor.

**Pediatric Patients:**

Promethazine HCl Injection is contraindicated for children under 2 years of age (see "WARNINGS - Use in Pediatric Patients").

In pediatric patients 2 years of age and older, the dosage should not exceed half that of the suggested adult dose. As an adjunct to premedication, the suggested dose is 0.5 mg per lb. of body weight in combination with an appropriately reduced dose of narcotic or barbiturate and the appropriate dose of an atropine-like drug. Antiemetics should not be used in vomiting of unknown etiology in pediatric patients (see "WARNINGS - Use in Pediatric Patients").

**HOW SUPPLIED**

Promethazine HCl Injection USP is available as follows:

25 mg/mL, 1 mL ampules, cartons of 25

50 mg/mL, 1 mL ampules, cartons of 25

Store at controlled room temperature 15°-30°C (59° - 86°F).

**Protect from light. Keep covered in carton until time of use.**



**Do not use if solution has developed color or contains a precipitate.**

Literature revised: June 2004

Product Nos.: 1107-81, 0259-81

**Watson Laboratories, Inc.**

Corona, CA 92880 USA

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## PROMETHAZINE HCL

promethazine hydrochloride injection

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0591-3157
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Promethazine hydrochloride (UNII: R61ZEH7I1I) (Promethazine - UNII:FF28EJQ494)		25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
Edetate Disodium (UNII: 7FLD91C86K)	0.1 mg in 1 mL
Calcium Chloride (UNII: M4I0D6VV5M)	0.04 mg in 1 mL
Sodium Metabisulfite ( )	0.25 mg in 1 mL
Phenol (UNII: 339NCG44TV)	5 mg in 1 mL
Water (UNII: 059QF0KO0R)	
Glacial Acetic Acid ( )	
Sodium Acetate, Trihydrate ( )	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0591-3157-83	25 in 1 CARTON		
1	NDC:0591-3157-54	1 mL in 1 AMPULE		

## PROMETHAZINE HCL

promethazine hydrochloride injection

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0591-3158
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Promethazine hydrochloride</b> (UNII: R61ZEH7I1I) (Promethazine - UNII:FF28EJQ494)		50 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	0.1 mg in 1 mL
<b>Calcium Chloride</b> (UNII: M4I0D6VV5M)	0.04 mg in 1 mL
<b>Sodium Metabisulfite</b> ()	0.25 mg in 1 mL
<b>Phenol</b> (UNII: 339NCG44TV)	5 mg in 1 mL
<b>Water</b> (UNII: 059QF0K00R)	
<b>Glacial Acetic Acid</b> ()	
<b>Sodium Acetate, Trihydrate</b> ()	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0591-3158-83	25 in 1 CARTON		
1	NDC:0591-3158-54	1 mL in 1 AMPULE		

**Labeler** - Watson Laboratories, Inc.

Revised: 4/2006

Watson Laboratories, Inc.