SANDOZ

May 18, 2012

Dear Healthcare Professional:

Due to the current critical shortage of phentolamine mesylate for injection, Sandoz is coordinating with the Food and Drug Administration (FDA) to increase the availability of this product during the shortage.

In conjunction with FDA, Sandoz has initiated temporary importation of phentolamine mesylate injection into the US market. The Sandoz phentolamine mesylate injection 5 mg/mL product contains the same active ingredient, phentolamine mesylate, as the phentolamine mesylate for injection 5 mg vial product approved in the United States. However, there are important differences between the US product and Canadian product that Healthcare providers should be aware of before prescribing and product preparation.

**The Sandoz Canada product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic 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 non-asthmatic people.**

**The Sandoz Canada product is a liquid dosage form and does not require reconstitution.**

**Key differences between the US marketed phentolamine mesylate for injection 5 mg and the imported phentolamine mesylate injection 5 mg/mL for Canadian market that you need to be aware of appear in the following table.**

| **Property** | **phentolamine mesylate for injection 5 mg (US)** | **phentolamine mesylate injection 5 mg/mL (Sandoz Canada)** |
|---|---|---|
| Active Ingredient Content | Phentolamine mesylate USP<br>5 mg/vial | Phentolamine mesylate<br>5 mg/mL |
| Inactive Ingredient Content | Mannitol 25 mg | Dextrose 38.3 mg (3.5 %)<br>**Sodium Metabisulfite** 0.6 mg<br>Glacial acetic acid<br>Anhydrous sodium acetate<br>Sodium hydroxide<br>Methanesulfonic acid<br>Water for Injection qs 1 mL |
| Dosage Form | Lyophilized<br>(requires reconstitution) | Liquid<br>(does not require reconstitution) |
| Storage | Controlled room temperature<br>15-30°C | **Refrigerate** between 2-8°C<br>Protect from light and heat |

Refer to the US package insert for full prescribing information. It is important to note that there is a difference in the formatting and content of the labeling between the US marketed phentolamine mesylate for injection and the Sandoz Canada Inc. phentolamine mesylate injection. A table highlighting key differences between the US product and the Sandoz product as well as a comparison of the content of the product labeling is attached.

The bar code on the labeling for phentolamine mesylate injection may not be appropriately recognized by scanning systems used in the United States. Institutions should confirm that barcode systems do not provide incorrect information when the product is scanned.

The phentolamine mesylate injection is manufactured in compliance with good manufacturing practices in Quebec, Canada at an FDA inspected facility, Sandoz Canada Inc.

At this time, FDA's exercise of enforcement discretion for the importation of Sandoz' phentolamine mesylate injection product is limited to Sandoz during the critical shortage of phentolamine mesylate injection. Importation or distribution of this product in the United States by any other entity is outside the scope of FDA's regulatory discretion, and FDA has not approved Sandoz' phentolamine mesylate injection product for marketing in the United States.

Effective immediately, Sandoz will offer the following version:

| | |
|---|---|
| Phentolamine Mesylate Injection 5 mg/mL | DIN 02243737 (Canadian authorization #) |
| 1 mL single use vials | Boxes of 10 |

ORDERING PRODUCT: Customers can call Sandoz Inc. Customer Service to find out how to order at 1.800.525.8747 (Monday to Friday 8:00 am- 5:30 pm EST).

QUESTIONS: Sandoz urges you to contact the Sandoz Canada Drug Information department at 1.800.343.8839 ext. 4636 (Monday to Friday 8:30 am- 4:30 pm EST) if you have any questions about the information contained in this letter or the safe and effective use of phentolamine mesylate injection.

To report adverse events, please call Sandoz Inc. at 1.800.525.8747 (Monday to Friday 8:00 am- 5:30 pm EST). Adverse events that may be related to the use of this product may also be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: Use postage paid FDA form 3500 available at : www.fda.gov/medwatch/getforms.htm
  Mail to MedWatch FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Sincerely,
**Sandoz Inc.**

Macdonald Marcy

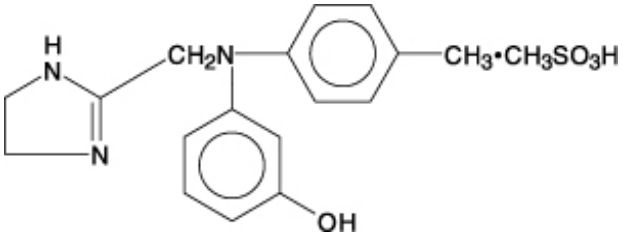
Digitally signed by Macdonald Marcy
DN: cn=Macdonald Marcy, ou=people, GX, serialNumber=1180655, dc=com, novartis
Date: 2012.05.18 16:41:38 -06'00'

Marcy Macdonald,
Senior Director
Regulatory Affairs

## Highlighted Product Comparison

| | US Product | Sandoz Product for Canada | Comment |
|---|---|---|---|
| Warnings | **Does not contain Sulfites** | **Contains Sulfites** | The Sandoz Canada product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic 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 non-asthmatic people. |
| Dosage and Administration<br><br>Please see page 8 and 9 of the insert comparison | Please see page 8 and 9 of the insert comparison | Please see page 8 and 9 of the insert comparison | Please see page 8 and 9 of the insert comparison |
| Labeled Storage Recommendations | Store at controlled room temperature, 15° to 30°C (59° to 86°F). | Refrigerate between 2 and 8°C. Protect from light and heat. | Follow the storage recommendation for the Sandoz Canada product |
| Product Preparation | Five milligrams of phentolamine mesylate is dissolved in 1 mL of Sterile Water for Injection. | Phentolamine Mesylate Injection is pre-dissolved and is already in aqueous form. | The Sandoz Canada product does not require dilution |
| Prescription Symbol | The US Product contains an Rx only symbol | [Not included] | This product is for Prescription Use Only in the US. |
| Language | English | French and English | The Sandoz product contains both French and English as required in Canada. |

**Insert Comparison**

| US Prescribing Information | Sandoz Label |
|---|---|
| **DESCRIPTION**<br>Phentolamine Mesylate for Injection USP, is an antihypertensive, available in vials for intravenous and intramuscular administration.<br><br>Each vial contains phentolamine mesylate USP, 5 mg and mannitol USP, 25 mg in sterile, lyophilized form.<br>Phentolamine mesylate is *m*-[*N*-(2-Imidazolin-2-ylmethyl)-*p*-toluidino]phenol monomethanesulfonate (salt), and its structural formula is:<br>  <br><br>Molecular Formula - $C_{17}H_{19}N_3O \cdot CH_4O_3S$ M.W. - 377.47<br>Phentolamine mesylate USP is a white or off-white, odorless crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and in alcohol, and slightly soluble in chloroform. It melts at about 178°C. | **AVAILABILITY OF DOSAGE FORMS**<br><br>Each mL of Phentolamine Mesylate Injection Sandoz Standard contains:<br>phentolamine mesylate 5 mg, dextrose 3.5%, sodium metabisulfite 0.6 mg, glacial acetic acid, anhydrous sodium acetate, sodium hydroxide and/or methanesulfonic acid to adjust pH and water for injection. |
| **CLINICAL PHARMACOLOGY**<br>Phentolamine mesylate produces an alpha-adrenergic block of relatively short duration. It also has direct, but less marked, positive inotropic and chronotropic effects on cardiac muscle and vasodilator effects on vascular smooth muscle.<br>Phentolamine has a half-life in the blood of 19 minutes following intravenous administration. Approximately 13% of a single intravenous dose appears in the urine as unchanged drug. | **ACTIONS AND CLINICAL PHARMACOLOGY**<br>Phentolamine produces an alpha-adrenergic block of relatively short duration. It also has direct but less marked positive inotropic and chronotropic effects on cardiac muscle and vasodilator effects on vascular smooth muscle. |

| US Prescribing Information | Sandoz Label |
|---|---|
| **INDICATIONS AND USAGE**<br>Phentolamine Mesylate for Injection is indicated for the prevention or control of hypertensive episodes that may occur in a patient with pheochromocytoma as a result of stress or manipulation during preoperative preparation and surgical excision.<br><br>Phentolamine Mesylate for Injection is indicated for the prevention or treatment of dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine.<br><br>Phentolamine Mesylate for Injection is also indicated for the diagnosis of pheochromocytoma by the phentolamine blocking test. | **INDICATIONS**<br>Phentolamine Mesylate Injection Sandoz Standard, is indicated in the following:<br>• Prevention and control of hypertensive episodes in patients with pheochromocytoma, preoperatively and during surgical excision.<br><br>• Prevention of dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine.<br><br>• Diagnosis of pheochromocytoma (phentolamine test). |
| **CONTRAINDICATIONS**<br>Myocardial infarction, history of myocardial infarction, coronary insufficiency, angina, or other evidence suggestive of coronary artery disease; hypersensitivity to phentolamine or related compounds. | **CONTRAINDICATIONS**<br>Phentolamine mesylate is contraindicated in the following:<br>• Myocardial infarction, history of myocardial infarction, coronary insufficiency, angina or other evidence suggestive of coronary artery disease.<br>• Hypotension.<br>• Hypersensitivity to phentolamine or related compounds. |
| **WARNINGS**<br>Myocardial infarction, cerebrovascular spasm, and cerebrovascular occlusion have been reported to occur following the administration of phentolamine, usually in association with marked hypotensive episodes.<br><br>For screening tests in patients with hypertension, the generally available urinary assay of catecholamines or other biochemical assays have largely replaced the phentolamine and other pharmacological tests for reasons of accuracy and safety. None of the chemical or pharmacological tests is infallible in the diagnosis of pheochromocytoma. The phentolamine blocking test is not the procedure of choice and should be reserved for cases in which additional confirmatory evidence is necessary and the relative risks involved in conducting the test have been considered. | **WARNINGS**<br>Blood pressure must be monitored for appropriate selection of patients, dosage, and duration of therapy. Myocardial infarction, cerebrovascular spasm, and cerebrovascular occlusion have been reported to occur following the administration of phentolamine, usually in association with marked hypotensive episodes with shock-like states which occasionally occur.<br>For screening tests in patients with hypertension, the generally available urinary assay of catecholamines or other biochemical assays have largely supplanted the phentolamine test and other pharmacological tests for reasons of accuracy and safety. None of the chemical or pharmacological tests are infallible in the diagnosis of pheochromocytoma. The phentolamine test is not the procedure of choice and should be reserved for cases in which additional confirmatory evidence is necessary, and the relative risks involved in conducting the test have been considered. |

| US Prescribing Information | Sandoz Label |
|---|---|
| **PRECAUTIONS**<br>**General**<br>Tachycardia and cardiac arrhythmias may occur with the use of phentolamine or other alpha-adrenergic blocking agents. When possible, administration of cardiac glycosides should be deferred until cardiac rhythm returns to normal.<br>**Drug Interactions**<br>See DOSAGE AND ADMINISTRATION. Diagnosis of pheochromocytoma, Preparation.<br>**Carcinogenesis, Mutagenesis, Impairment of Fertility**<br>Long-term carcinogenicity studies, mutagenicity studies, and fertility studies have not been conducted with phentolamine.<br>**Pregnancy**<br>Teratogenic Effects-Pregnancy Category C<br>Administration of phentolamine to pregnant rats and mice at oral doses 24 to 30 times the usual daily human dose (based on a 60 kg human) resulted in slightly decreased growth and slight skeletal immaturity of the fetuses. Immaturity was manifested by increased incidence of incomplete or unossified calcanei and phalangeal nuclei of the hind limb and of incompletely ossified sternebrae. At oral doses 60 times the usual daily human dose (based on a 60 kg human), a slightly lower rate of implantation was found in the rat. Phentolamine did not affect embryonic or fetal development in the rabbit at oral doses 20 times the usual daily human dose (based on a 60 kg human). No teratogenic or embryo-toxic effects were observed in the rat, mouse, or rabbit studies.<br>There are no adequate and well-controlled studies in pregnant women. Phentolamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.<br>**Nursing Mothers**<br>It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from phentolamine, 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.<br>**Pediatric Use**<br>See DOSAGE AND ADMINISTRATION. | **PRECAUTIONS**<br>Tachycardia and cardiac arrhythmias may occur with the use of phentolamine or other alpha-adrenergic blocking agents. When possible, defer administration of cardiac glycosides until cardiac rhythm returns to normal.<br>Due to its stimulatory effect on the gastrointestinal tract, including gastric secretion, phentolamine should be used with caution in patients with gastritis or peptic ulcer.<br>Use caution in administering phentolamine to patients with renal impairment; since the drug is primarily excreted by the kidney, a reduction in dosage may be necessary.<br>**Pregnancy and Lactation**<br>Animal studies indicate that high doses of phentolamine to pregnant rats and mice resulted in slightly decreased growth and slight skeletal immaturity in the fetuses. At very high doses a slightly lower rate of implantation was found in the rat. There are no studies in pregnant or nursing women. The use of phentolamine is therefore not recommended unless the potential benefits justify the potential risks.<br>**Occupational Hazards**<br>Phentolamine may cause central nervous symptoms, e.g. dizziness, which may impair the patient's reactions. Patients must therefore be warned against engaging in activities that require quick reactions, such as driving motor vehicles or operating machines.<br>**Drug Interactions**<br>See **DOSAGE AND ADMINISTRATION**, **Diagnosis of Pheochromocytoma, Preparation.** |

| US Prescribing Information | Sandoz Label |
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| **ADVERSE REACTIONS**<br>Acute and prolonged hypotensive episodes, tachycardia, and cardiac arrhythmias have been reported. In addition, weakness, dizziness, flushing, orthostatic hypotension, nasal stuffiness, nausea, vomiting, and diarrhea may occur. | **ADVERSE REACTIONS**<br>Orthostatic hypotension and tachycardia occur frequently. Acute and prolonged hypotensive episodes and cardiac arrhythmias have been reported (see **WARNINGS**). In addition, weakness, dizziness, flushing, nasal stuffiness, nausea, vomiting, diarrhea, anorexia, abdominal discomfort, conjunctival infections, sedation, angina pain, and precordial pain may occur.<br>Priapism, penile hematoma and fibrosis have been reported following local injection. Neither the route of administration nor this use are approved or recommended. |
| **OVERDOSAGE**<br>**Acute Toxicity**<br>No deaths due to acute poisoning with phentolamine have been reported.<br>Oral $LD_{50}$'s (mg/kg): mice, 1000; rats, 1250.<br>**Signs and Symptoms**<br>Overdosage with phentolamine is characterized chiefly by cardiovascular disturbances, such as arrhythmias, tachycardia, hypotension, and possibly shock. In addition, the following might occur: excitation, headache, sweating, pupillary contraction, visual disturbances; nausea, vomiting, diarrhea; hypoglycemia.<br>**Treatment**<br>There is no specific antidote.<br>A decrease in blood pressure to dangerous levels or other evidence of shock like conditions should be treated vigorously and promptly. The patient's legs should be kept raised and a plasma expander should be administered. If necessary, intravenous infusion or norepinephrine, titrated to maintain blood pressure at the normotensive level, and all available supportive measures should be included.<br>Epinephrine should not be used, since it may cause a paradoxical reduction in blood pressure. | **OVERDOSAGE: SYMPTOMS AND TREATMENT**<br>Death has occurred following use of phentolamine 5 mg for diagnostic purposes; fatal reactions do not appear to be related to the presence/absence of pheochromocytoma. A 47 year old man survived 440 mg infused in one day.<br>**Symptoms**<br>The main clinical manifestations of overdosage with phentolamine are arterial hypotension, tachycardia, cardiac stimulation, arrhythmias, increase in systemic venous capacity, and possibly shock. These effects may be accompanied by headache, hyper-excitability and visual disturbances, sweating, increased gastric motility, vomiting and diarrhea, hypoglycemia.<br>**Treatment**<br>Severe hypotension should be treated by discontinuing treatment with phentolamine and maintaining the patient in the supine position with the feet raised.<br>Norepinephrine, cautiously titrated in continuous IV infusion, can be considered the pharmacological antagonist. The effect of phentolamine may wear off in a short time and administration of norepinephrine may have to be adjusted accordingly. Do not use epinephrine since this may cause a further fall in blood pressure. The ECG should be monitored when a pressor agent is used because major arrhythmias may occur. Should excessive cardiac stimulation and hypertensive crisis arise, administer a beta blocking agent by slow IV infusion.<br>Treat hypoglycemia with IV glucose until compensated. |

| US Prescribing Information | Sandoz Label |
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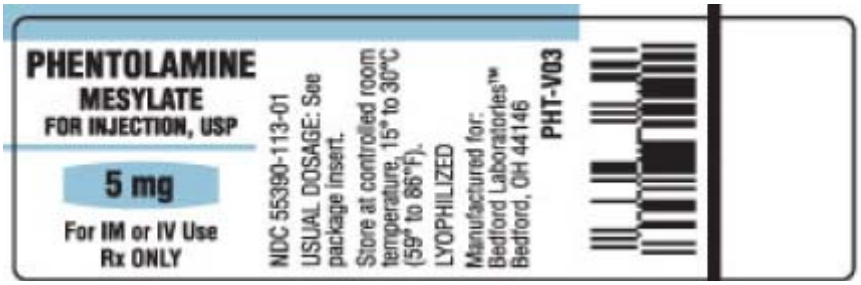
| **DOSAGE AND ADMINISTRATION**<br>*The reconstituted solution should be used upon preparation and should not be stored.*<br>1. **Prevention or control of hypertensive episodes in the patient with pheochromocytoma.** For preoperative reduction of elevated blood pressure, 5 mg of phentolamine mesylate (1 mg for children) is injected intravenously or intramuscularly 1 or 2 hours before surgery, and repeated if necessary.<br>During surgery, phentolamine mesylate (5 mg for adults, 1 mg for children) is administered intravenously as indicated, to help prevent or control paroxysms of hypertension, tachycardia, respiratory depression, convulsions, or other effects of epinephrine intoxication. (Postoperatively, norepinephrine may be given to control the hypotension that commonly follows complete removal of a pheochromocytoma.) | **DOSAGE AND ADMINISTRATION**<br>**Prevention or control of hypertensive episodes in the patient with pheochromocytoma, preoperatively and during surgical excision.**<br>For use in preoperative reduction of elevated blood pressure, inject 2 to 5 mg of Phentolamine Mesylate Injection Sandoz Standard IV or IM 1 or 2 hours before surgery (and repeat if necessary). For children, use the minimum effective dose e.g. 1 mg for a child over 8 years old.<br>During surgical removal of pheochromocytoma, repeat IV Phentolamine Mesylate Injection Sandoz Standard as indicated to help prevent or control paroxysms of hypertension, respiratory depression, convulsions, or other effects of epinephrine intoxication. (Postoperatively, norepinephrine may be given to control the hypotension which commonly follows complete removal of a pheochromocytoma). |
| 2. **Prevention or treatment of dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine.**<br>*For Prevention:* 10 mg of phentolamine mesylate is added to each liter of solution containing norepinephrine. The pressor effect of norepinephrine is not affected.<br>*For Treatment:* 5 to 10 mg of phentolamine mesylate in 10 mL of saline is injected into the area of extravasation within 12 hours. | **Prevention of dermal necrosis and sloughing following IV administration or extravasation of norepinephrine.**<br>Infiltrate Phentolamine Mesylate Injection Sandoz Standard (5 to 10 mg in 10 mL saline) into the area of extravasation within 12 hours. |
| 3. **Diagnosis of pheochromocytoma - phentolamine blocking test**.<br>The test is most reliable in detecting pheochromocytoma in patients with sustained hypertension and least reliable in those with paroxysmal hypertension. False-positive tests may occur in patients with hypertension without pheochromocytoma. | **Diagnosis of pheochromocytoma (phentolamine test)** The test is most reliable in detecting pheochromocytoma in patients with sustained hypertension, and least reliable in those with paroxysmal hypertension. False positive tests may occur in patients with hypertension without pheochromocytoma. |
| **a. Intravenous**<br>Preparation<br>The CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS sections should be reviewed. Sedatives, analgesics, and all other medications except those that might be deemed essential (such as digitalis and insulin) are withheld for at least 24 hours, and preferably 48 to 72 hours, prior to the test. Antihypertensive drugs are withheld until blood pressure returns to the untreated, hypertensive level. This test is not performed on a patient who is normotensive. | **Intravenous**<br>**Preparation: Review the CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS.**<br>Withhold all medication such as sedatives, analgesics, and all other medication unless deemed essential (e.g. digitalis and insulin) for at least 24 hours (preferably 48 to 72 hours) prior to the test. Special precautions should be taken with agents that have a long half-life and may interact with phentolamine (e.g. guanethidine, reserpine and antidepressants). Withhold antihypertensive drugs until blood pressure returns to the untreated, hypertensive level. Do not perform test on a patient who is normotensive. |
| Procedure<br>The patient is kept at rest in a supine position throughout the test, preferably in a quiet, darkened room. Injection of phentolamine is delayed until blood pressure is stabilized, as evidenced by blood pressure readings taken every 10 minutes for at least 30 minutes. Five milligrams of phentolamine mesylate is dissolved in 1 mL of Sterile Water for Injection. The dose for adults is 5 mg; for children, 1 mg.<br>The syringe needle is inserted into the vein, and injection is delayed until pressor response to venipuncture has subsided. Phentolamine is injected rapidly. Blood pressure is recorded immediately after injection, at 30-second intervals for the first 3 minutes, and at 60-second intervals for the next 7 minutes. | **Procedure**<br>• Keep patient at rest in the supine position throughout the test, preferably in a quiet, darkened room. Delay Phentolamine Mesylate Injection Sandoz Standard until blood pressure is stabilized, as evidenced by blood pressure readings taken every 10 minutes for at least one-half hour.<br>• Phentolamine Mesylate Injection Sandoz Standard contains phentolamine mesylate 5 mg dissolved in 1 mL of sterile water for injection.<br>Dose for adults is 5 mg; for children, 1 mg.<br>• Insert the syringe needle into vein, delay injection until pressor response to venipuncture has subsided.<br>• Inject Phentolamine Mesylate Injection Sandoz Standard rapidly. Record blood pressure immediately after injection, at 30-second intervals for the first 3 minutes, and at 60-second intervals for the next 7 minutes. |

| US Prescribing Information | Sandoz Label |
|---|---|
| **(DOSAGE AND ADMINISTRATION continued)**<br>Interpretation<br>A positive response, suggestive of pheochromocytoma, is indicated when the blood pressure is reduced more than 35 mm Hg systolic and 25 mm Hg diastolic. A typical positive response is a reduction in pressure of 60 mm Hg systolic and 25 mm Hg diastolic. Usually, maximal effect is evident within 2 minutes after injection. A return to pre-injection pressure commonly occurs within 15 to 30 minutes but may occur more rapidly.<br>If blood pressure decreases to a dangerous level, the patient should be treated as outlined under OVERDOSAGE.<br>A positive response should always be confirmed by other diagnostic procedures, preferably by measurement of urinary catecholamines or their metabolites.<br>A negative response is indicated when the blood pressure is elevated, unchanged, or reduced less than 35 mm Hg systolic and 25 mm Hg diastolic after injection of phentolamine. A negative response to this test does not exclude the diagnosis of pheochromocytoma, especially in patients with paroxysmal hypertension in whom the incidence of false-negative responses is high.<br>**b. Intramuscular**<br>If the intramuscular test for pheochromocytoma is preferred, preparation is the same as for the intravenous test. Five milligrams of phentolamine mesylate is then dissolved in 1 mL of Sterile Water for Injection. The dose for adults is 5 mg intramuscularly; for children, 3 mg. Blood pressure is recorded every 5 minutes for 30 to 45 minutes following injection. A positive response is indicated when the blood pressure is reduced 35 mm Hg systolic and 25 mm Hg diastolic, or more, within 20 minutes following injection.<br>*Note:* Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. | **(DOSAGE AND ADMINISTRATION continued)**<br>**Interpreting the Test**<br>**Positive response,** suggestive of pheochromocytoma, is indicated by a drop in blood pressure of more than 35 mm Hg systolic and 25 mm Hg diastolic pressure. A typical positive response may be a drop of 60 mm Hg systolic and 25 mm Hg diastolic. Maximal depressor pressure effect usually is evident within 2 minutes after injection. Return to pre-injection pressure commonly occurs within 15 to 30 minutes, but may return more rapidly.<br>If blood pressure falls to a dangerous level, treat patient as outlined under **OVERDOSAGE**.<br>A positive response should always be confirmed by other diagnostic procedures, preferably the measurement of urinary catecholamines or their metabolites.<br>**Negative response** is indicated when the blood pressure is unchanged, elevated, or is reduced less than 35 mm Hg systolic and 25 mm Hg diastolic after injection of Phentolamine Mesylate Injection Sandoz Standard. A negative response to this test does not exclude the diagnosis of pheochromocytoma, especially in patients with paroxysmal hypertension in whom the incidence of false negative responses is high.<br>**Intramuscular**<br>If the IM test for pheochromocytoma is preferred, preparation is the same as for the IV test. Dose for adults is 5 mg IM, for children, 3 mg. Record blood pressure every 5 minutes for 40 to 45 minutes following IM injection. Positive response is indicated by a drop in blood pressure of 35 mm Hg systolic and 25 mm Hg diastolic or greater within 20 minutes following injection. |

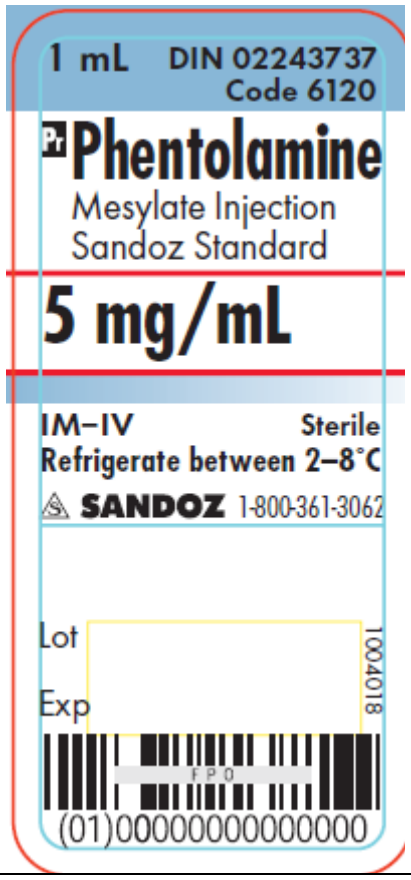
| US Prescribing Information | Sandoz Label |
|---|---|
| **HOW SUPPLIED**<br>Phentolamine Mesylate for Injection USP, 5 mg, for intramuscular or intravenous use, is supplied in a 2mL vial and individually boxed. **NDC 55390-113-01.**<br>The reconstituted solution should be used upon preparation and should not be stored.<br>Store at controlled room temperature, 15° to 30°C (59° to 86°F). | Phentolamine Mesylate Injection Sandoz Standard is available in 1 mL vials, boxes of 10.<br>**Refrigerate between 2 and 8°C.**<br>**Protect from light and heat.**<br>**Discard unused portion.**<br>Do not use if the solution becomes discolored. |

**Vial Label Comparison**

US Vial Label

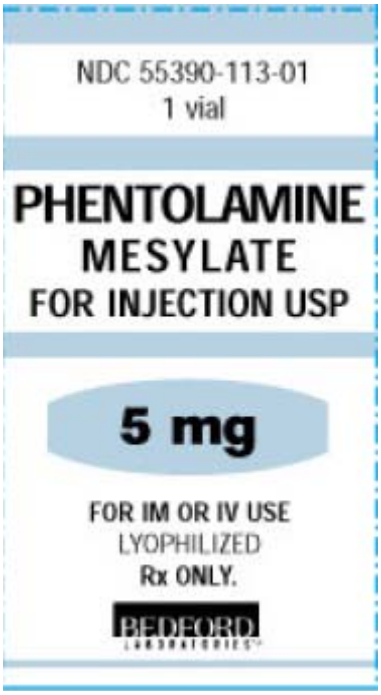



Sandoz Vial Label

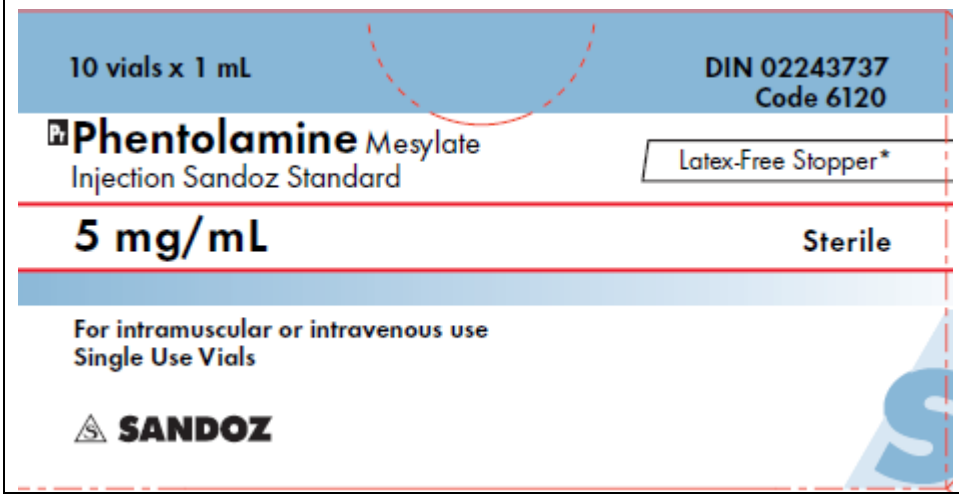


**Carton Label Comparison**

US Carton Label- Primary Display Panel




Sandoz Carton Label- English Primary Display Panel



US Carton Label- Back and Side Panels

USUAL DOSAGE: See package insert.

Each vial contains: phentolamine mesylate USP 5 mg and 25 mg mannitol in lyophilized form.

Manufactured by:
Ben Venue Labs, Inc.
Bedford, OH 44146

Manufactured for:
Bedford Laboratories™
Bedford, OH 44146

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

The reconstituted solution should be used upon preparation and should not be stored.

Sandoz Carton Label- English Side Panel

**Phentolamine** Mesylate Injection
Sandoz Standard
**IM–IV**
For dosage, administration and detailed directions for use, see package insert.
**Dosage: Preoperative reduction of elevated blood pressure–** Adults: 2 to 5 mg IM or IV, 1 or 2 hours before surgery. Repeat if necessary. Children: inject minimum effective dosage; e.g., 1 mg for a child over 8 years old. **To prevent dermal necrosis following IV administration or extravasation of norepinephrine–** Further dilute 5 or 10 mg to 10 mL with normal saline. Infiltrate into the area of extravasation within 12 hours. **Diagnosis of pheochromocytoma:** Adults: 5 mg IM or IV. Children: 1 mg IV or 3 mg IM.
**Each mL contains:** phentolamine mesylate 5 mg, dextrose 3.5%, sodium metabisulfite 0.6 mg, glacial acetic acid, anhydrous sodium acetate, sodium hydroxide or methanesulfonic acid to adjust pH and water for injection.
**Refrigerate between 2 and 8°C. Protect from light and heat.**
**Discard unused portion.**
* Stopper contains no dry natural rubber.

**Sandoz Canada Inc.** Qc, Canada J4B 7K8
? 1-800-361-3062