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<tr>
<td><strong>Application</strong></td>
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<tr>
<td><strong>Supplement Number</strong></td>
<td>006695</td>
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</tr>
<tr>
<td><strong>Box Warning</strong></td>
<td>MUSTARGEN (methylcellulose NCS) should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents. This drug is HIGHLY TOXIC and both powder and solution must be handled and administered with care. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Due to the toxic properties of methylcellulose (e.g., corrosivity, carcinogenicity, mutagenicity, teratogenicity), special handling procedures should be reviewed prior to handling and followed diligently. Extravasation of the drug into subcutaneous tissues results in a painful inflammation. The area usually becomes edematous and sloughing may occur. If leakage of drug is obvious, prompt neutralization of the area with sterile isotonic sodium bicarbonate (2.5% solution) and application of an ice compress for 6 to 12 hours may minimize the local reaction. For a 1:6 molar solution of sodium bicarbonate, use 4.14 g of sodium bicarbonate per 100 mL of Sterile Water for Injection or 2.64 g of sodium bicarbonate per 100 mL of Sterile Water for Injection.</td>
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<tr>
<td><strong>Boxed Warning</strong></td>
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<tr>
<td><strong>Complete Label</strong></td>
<td>MUSTARGEN</td>
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</tr>
<tr>
<td><strong>Description</strong></td>
<td>MUSTARGEN, an anti-cancer nitroso mustard, also known as HN2 hydrochloride, is a nitrogen analog of sulfur</td>
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</table>
Select Prescribe for how someone prescribing a medication such as a physician may view the product label section order. Select Prepare for how someone preparing a medication such as a pharmacist or nurse may view the sections. Select Administer for how someone administering a medication such as a nurse or patient may view the sections. Please send any errors, omissions, and comments to Send Comment.

### Prescribe
**Application**

**Supplement Number** 006695

**Box Warning**

MUSTARGEN (Mechlorethamine HCl) should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents. This drug is HIGHLY TOXIC and both powder and solution must be handled and administered with care. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Due to the toxic properties of mechlorethamine (e.g., corrosivity, carcinogenicity, mutagenicity, teratogenicity), special handling procedures should be reviewed prior to handling and followed diligently. Extravasation of the drug into subcutaneous tissues results in a painful inflammation. The area usually becomes indurated and sloughing may occur. If leakage of drug is obvious, prompt infiltration of the area with sterile isotonic sodium thiosulfate (1/6 molar) and application of an ice compress for 6 to 12 hours may minimize the local reaction. For a 1/6 molar solution of sodium thiosulfate, use 4.14 g of sodium thiosulfate per 100 mL of Sterile Water for Injection or 2.64 g of anhydrous sodium thiosulfate per 100 mL or dilute 4 mL of Sodium Thiosulfate Injection (10%) with 6 mL of Sterile Water for Injection.

### Prepare

**Boxed Warning**

MUSTARGEN (Mechlorethamine HCl) should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents. This drug is HIGHLY TOXIC and both powder and solution must be handled and administered with care. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Due to the toxic properties of mechlorethamine (e.g., corrosivity, carcinogenicity, mutagenicity, teratogenicity), special handling procedures should be reviewed prior to handling and followed diligently. Extravasation of the drug into subcutaneous tissues results in a painful inflammation. The area usually becomes indurated and sloughing may occur. If leakage of drug is obvious, prompt infiltration of the area with sterile isotonic sodium thiosulfate (1/6 molar) and application of an ice compress for 6 to 12 hours may minimize the local reaction. For a 1/6 molar solution of sodium thiosulfate, use 4.14 g of sodium thiosulfate per 100 mL of Sterile Water for Injection or 2.64 g of anhydrous sodium thiosulfate per 100 mL or dilute 4 mL of Sodium Thiosulfate Injection (10%) with 6 mL of Sterile Water for Injection.

### Administer

**Complete Label**

**Formatted in PDF** MUSTARGEN

**Description**

MUSTARGEN, an antineoplastic nitrogen mustard also known as HN2 hydrochloride, is a nitrogen analog of sulfur mustard. It is a light yellow brown, crystalline, hygroscopic powder that is very soluble in water and also soluble in alcohol. Mechlorethamine hydrochloride is designated chemically as 2-chloro-N-(2-chloroethyl)-N-methylthalamine hydrochloride. The molecular weight is 192.52 and the melting point is 108-111°C. The empirical formula is C5H11Cl2N+•HCl, and the structural formula is: CH3N(CH2CH2Cl)2•HCl. Trituration of MUSTARGEN is a sterile, light yellow brown crystalline powder for injection by the intravenous or intracavitary routes after dissolution. Each vial of MUSTARGEN contains 10 mg of mechlorethamine hydrochloride triturated with sodium chloride q.s. 100 mg. When dissolved with 10 mL Sterile Water for Injection or 0.9% Sodium...
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<th><strong>Product Label</strong></th>
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<tr>
<td>Chloride Injection, the resulting solution has a pH of 3-5 at a concentration of 1 mg mechlorethamine HCl per mL.</td>
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<tr>
<td><strong>Generic Drug Name</strong></td>
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<tr>
<td><strong>Manufacturer</strong></td>
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<tr>
<td><strong>Distributor</strong></td>
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<td><strong>Clinical Pharmacology</strong></td>
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http://www.accessdata.fda.gov/scripts/cder/onctools/labels.cfm?GN=mechlorethamine,20ni...
studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

Precautions

General This drug is HIGHLY TOXIC and both powder and solution must be handled and administered with care. (See boxed warning and DOSAGE AND ADMINISTRATION: Special Handling.) Since MUSTARGEN is a powerful vesicant, it is intended primarily for intravenous use, and in most cases is given by this route. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Appropriate protective equipment should be worn when handling MUSTARGEN. Should accidental eye contact occur, copious irrigation for at least 15 minutes with water, normal saline or a balanced salt ophthalmic irrigating solution should be instituted immediately, followed by prompt ophthalmologic consultation. Should accidental skin contact occur, the affected part must be irrigated immediately with copious amounts of water, for at least 15 minutes while removing contaminated clothing and shoes, followed by 2% sodium thiosulfate solution. Medical attention should be sought immediately. Contaminated clothing should be destroyed. (See DOSAGE AND ADMINISTRATION: Special Handling.) Because of the toxicity of MUSTARGEN, and the unpleasant side effects following its use, the potential risk and discomfort from the use of this drug in patients with inoperable neoplasms or in the terminal stage of the disease must be balanced against the limited gain obtainable. These gains will vary with the nature and the status of the disease under treatment. The routine use of MUSTARGEN in all cases of widely disseminated neoplasms is to be discouraged. The use of MUSTARGEN in patients with leukopenia, thrombocytopenia, and anemia, due to invasion of the bone marrow by tumor carries a greater risk. In such patients a good response to treatment with disappearance of the tumor from the bone marrow may be associated with improvement of bone marrow function. However, in the absence of a good response or in patients who have been previously treated with chemotherapeutic agents, hematopoiesis may be further compromised, and leukopenia, thrombocytopenia and anemia may become more severe and lead to the demise of the patient. Tumors of bone and nervous tissue have responded poorly to therapy. Results are unpredictable in disseminated and malignant tumors of different types. Precautions must be observed with the use of MUSTARGEN and x-ray therapy or other chemotherapy in alternating courses. Hematopoietic function is characteristically depressed by either form of therapy, and neither MUSTARGEN following x-ray therapy nor x-ray therapy subsequent to the drug should be given until bone marrow function has recovered. In particular, irradiation of such areas as sternum, ribs, and vertebrae shortly after a course of nitrogen mustard may lead to hematologic complications. MUSTARGEN has been reported to have immunosuppressive activity. Therefore, it should be borne in mind that use of the drug may predispose the patient to bacterial, viral or fungal infection. Hyperuricemia may develop during therapy with
MUSTARGEN. The problem of urate precipitation should be anticipated, particularly in the treatment of the lymphomas, and adequate methods for control of hyperuricemia should be instituted and careful attention directed toward adequate fluid intake before treatment. Since drug toxicity, especially sensitivity to bone marrow failure, seems to be more common in chronic lymphatic leukemia than in other conditions, the drug should be given in this condition with great caution, if at all. Extreme caution must be used in exceeding the average recommended dose. (See OVERDOSAGE.) Laboratory Tests Many abnormalities of renal, hepatic, and bone marrow function have been reported in patients with neoplastic disease and receiving mechlorethamine. It is advisable to check renal, hepatic, and bone marrow functions frequently.

Carcinogenesis, Mutagenesis, Impairment of Fertility Therapy with alkylating agents such as MUSTARGEN may be associated with an increased incidence of a second malignant tumor, especially when such therapy is combined with other antineoplastic agents or radiation therapy. The International Agency for Research on Cancer has judged that mechlorethamine is a probable carcinogen in humans. This is supported by limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals. Young-adult female RF mice were injected intravenously with four doses of 2.4 mg/kg of mechlorethamine (0.1% solution) at 2-week intervals with observations for up to 2 years. An increased incidence of thymic lymphomas and pulmonary adenomas was observed. Painting mechlorethamine on the skin of mice for periods up to 33 weeks resulted in squamous cell tumors in 9 of 33 mice. Mechlorethamine induced mutations in the Ames test, in E. coli, and Neurospora crassa. Mechlorethamine caused chromosome aberrations in a variety of plant and mammalian cells. Dominant lethal mutations were produced in ICR/Ha Swiss mice. Mechlorethamine impaired fertility in the rat at a daily dose of 500 mg/kg intravenously for two weeks. Pregnancy Pregnancy Category D. See WARNINGS: Usage in Pregnancy. Nursing Mothers 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 MUSTARGEN, 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. Pediatric Use Safety and effectiveness in pediatric patients have not been established by well-controlled studies. Use of MUSTARGEN in pediatric patients has been quite limited. MUSTARGEN has been used in Hodgkin's disease, stages III and IV, in combination with other oncolytic agents (MOPP schedule). The MOPP chemotherapy combination includes mechlorethamine, vincristine, procarbazine, and prednisone or prednisolone. 2,3

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<th>Adverse Reactions</th>
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| Clinical use of MUSTARGEN usually is accompanied by toxic manifestations. Local Toxicity Thrombosis and thrombophlebitis may result from direct contact of the drug with the intima of the injected vein. Avoid high concentration and prolonged contact with the drug, especially in cases of elevated pressure in the antecubital vein (e.g., in
mediastinal tumor compression from severe vena cava syndrome).
Systemic Toxicity General: Hypersensitivity reactions, including
anaphylaxis, have been reported. Nausea, vomiting and depression of
formed elements in the circulating blood are dose-limiting side effects
and usually occur with the use of full doses of MUSTARGEN. Jaundice,
alopecia, vertigo, tinnitus and diminished hearing may occur
infrequently. Rarely, hemolytic anemia associated with such diseases as
the lymphomas and chronic lymphocytic leukemia may be precipitated
by treatment with alkylating agents including MUSTARGEN. Also,
various chromosomal abnormalities have been reported in association
with nitrogen mustard therapy. MUSTARGEN is given preferably at
night in case sedation for side effects is required. Nausea and vomiting
usually occur 1 to 3 hours after use of the drug. Emesis may disappear in
the first 8 hours, but nausea may persist for 24 hours. Nausea and
vomiting may be so severe as to precipitate vascular accidents in patients
with a hemorrhagic tendency. Premedication with antiemetics, in
addition to sedatives, may help control severe nausea and vomiting.
Anorexia, weakness and diarrhea may also occur. Hematologic: The
usual course of MUSTARGEN (total dose of 0.4 mg/kg either given as a
single intravenous dose or divided into two or four daily doses of 0.2 or
0.1 mg/kg, respectively) generally produces a lymphocytopenia within
24 hours after the first injection; significant granulocytopenia occurs
within 6 to 8 days and lasts for 10 days to 3 weeks. Agranulocytosis
appears to be relatively infrequent and recovery from leukopenia in most
cases is complete within two weeks of the maximum reduction.
Thrombocytopenia is variable but the time course of the appearance and
recovery from reduced platelet counts generally parallels the sequence of
granulocyte levels. In some cases severe thrombocytopenia may lead to
bleeding from the gums and gastrointestinal tract, petechiae, and small
subcutaneous hemorrhages; these symptoms appear to be transient and in
most cases disappear with return to a normal platelet count. However, a
severe and even uncontrollable depression of the hematopoietic system
occasionally may follow the usual dose of MUSTARGEN, particularly
in patients with widespread disease and debility and in patients
previously treated with other antineoplastic agents or x-ray. Persistent
pancytopenia has been reported. In rare instances, hemorrhagic
complications may be due to hyperheparinemia. Erythrocyte and
hemoglobin levels may decline during the first 2 weeks after therapy but
rarely significantly. Depression of the hematopoietic system may be
found up to 50 days or more after starting therapy. Integumentary:
Occasionally, a maculopapular skin eruption occurs, but this may be
idiosyncratic and does not necessarily recur with subsequent courses of
the drug. Erythema multiforme has been observed. Herpes zoster, a
common complicating infection in patients with lymphomas, may first
appear after therapy is instituted and on occasion may be precipitated by
treatment. Further treatment should be discontinued during the acute
phase of this illness to avoid progression to generalized herpes zoster.
Reproductive: Since the gonads are susceptible to MUSTARGEN,
treatment may be followed by delayed catamenia, oligomenorrhea, or
temporary or permanent amenorrhea. Impaired spermatogenesis,
azoospermia, and total germinal aplasia have been reported in male
patients treated with alkylating agents, especially in combination with other drugs. In some instances spermatogenesis may return in patients in remission, but this may occur only several years after intensive chemotherapy has been discontinued. Patients should be warned of the potential risk to their reproductive capacity.

<table>
<thead>
<tr>
<th>Overdosage</th>
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<td>With total doses exceeding 0.4 mg/kg of body weight for a single course, severe leukopenia, anemia, thrombocytopenia and a hemorrhagic diathesis with subsequent delayed bleeding may develop. Death may follow. The only treatment in instances of excessive dosage appears to be repeated blood product transfusions, antibiotic treatment of complicating infections and general supportive measures. The intravenous LD50 of MUSTARGEN is 2 mg/kg and 1.6 mg/kg in the mouse and rat, respectively.</td>
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<th>Summary</th>
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| Intravenous Administration The dosage of MUSTARGEN varies with the clinical situation, the therapeutic response and the magnitude of hematologic depression. A total dose of 0.4 mg/kg of body weight for each course usually is given either as a single dose or in divided doses of 0.1 to 0.2 mg/kg per day. Dosage should be based on ideal dry body weight. The presence of edema or ascites must be considered so that dosage will be based on actual weight unaugmented by these conditions. The margin of safety in therapy with MUSTARGEN is narrow and considerable care must be exercised in the matter of dosage. Repeated examinations of blood are mandatory as a guide to subsequent therapy. (See OVERDOSE.) Within a few minutes after intravenous injection, MUSTARGEN undergoes chemical transformation, combines with reactive compounds, and is no longer present in its active form in the blood stream. Subsequent courses should not be given until the patient has recovered hematologically from the previous course; this is best determined by repeated studies of the peripheral blood elements awaiting their return to normal levels. It is often possible to give repeated courses of MUSTARGEN as early as three weeks after treatment. Preparation of Solution for Intravenous Administration This drug is HIGHLY TOXIC and both powder and solution must be handled and administered with care. (See DESCRIPTION : BOXED WARNING and Special Handling.) Since MUSTARGEN is a powerful vesicant, it is intended primarily for intravenous use, and in most cases is given by this route. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. Appropriate protective equipment should be worn when handling MUSTARGEN. Should accidental eye contact occur, copious irrigation for at least 15 minutes with water, normal saline or a balanced salt ophthalmic irrigating solution should be instituted immediately, followed by prompt ophthalmologic consultation. Should accidental skin contact occur, the affected part must be irrigated immediately with copious amounts of water, for at least 15 minutes while removing contaminated clothing and shoes, followed by 2% sodium thiosulfate solution. Medical attention should be sought immediately. Contaminated clothing should be
destroyed. (See Special Handling.) Each vial of MUSTARGEN contains 10 mg of mechloretamine hydrochloride triturated with sodium chloride q.s. 100 mg. In neutral or alkaline aqueous solution it undergoes rapid chemical transformation and is highly unstable. Although solutions prepared according to instructions are acidic and do not decompose as rapidly, they should be prepared immediately before each injection since they will decompose on standing. When reconstituted, MUSTARGEN is a clear colorless solution. Do not use if the solution is discolored or if droplets of water are visible within the vial prior to reconstitution. Using a sterile 10 mL syringe, inject 10 mL of Sterile Water for Injection or 10 mL Sodium Chloride Injection into a vial of MUSTARGEN. With the needle (syringe attached) still in the rubber stopper, shake the vial several times to dissolve the drug completely. The resultant solution contains 1 mg of mechloretamine hydrochloride per mL. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Special Handling Animal studies have shown mechloretamine to be corrosive to skin and eyes, a powerful vesicant, irritating to the mucous membranes of the respiratory tract and highly toxic by the oral route. It has also been shown to be carcinogenic, mutagenic and teratogenic. Due to the drug’s toxic properties, appropriate precautions including the use of appropriate safety equipment are recommended for the preparation of MUSTARGEN for parenteral administration. Inhalation of dust or vapors and contact with skin or mucous membranes, especially those of the eyes, must be avoided. The National Institutes of Health presently recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet. Personnel preparing drugs of this class should wear chemical resistant, impervious gloves, safety goggles, outer garments and shoe covers. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces and inhalation of vapors and dust. Appropriate techniques should be used to remove potentially contaminated clothing. Several other guidelines for proper handling and disposal of antineoplastic drugs have been published and should be considered. Accidental Contact Measures Should accidental eye contact occur, copious irrigation for at least 15 minutes with water, normal saline or a balanced salt ophthalmic irrigating solution should be instituted immediately, followed by prompt ophthalmologic consultation. Should accidental skin contact occur, the affected part must be irrigated immediately with copious amounts of water, for at least 15 minutes while removing contaminated clothing and shoes, followed by 2% sodium thiosulfate solution. Medical attention should be sought immediately. Contaminated clothing should be destroyed. (See PRECAUTIONS: General and DOSAGE AND ADMINISTRATION: Preparation of Solution for Intravenous Administration.) Technique for Intravenous Administration Withdraw into the syringe the calculated volume of solution required for a single injection. Dispose of any remaining solution after neutralization (see below). Although the drug may be injected directly into any suitable vein, it is injected preferably into the rubber or plastic tubing of a flowing intravenous infusion set.
This reduces the possibility of severe local reactions due to extravasation or high concentration of the drug. Injecting the drug into the tubing rather than adding it to the entire volume of the infusion fluid minimizes a chemical reaction between the drug and the solution. The rate of injection apparently is not critical provided it is completed within a few minutes. Intracavitary Administration Nitrogen mustard has been used by intracavitary administration with varying success in certain malignant conditions for the control of pleural, 4-13 peritoneal, 5,6,9,11-16 and pericardial, 5,11-13 effusions caused by malignant cells. The technique and the dose used by any of these routes varies. Therefore, if MUSTARGEN is given by the intracavitary route, the published articles concerning such use should be consulted. Because of the inherent risks involved, the physician should be experienced in the appropriate injection techniques, and be thoroughly aware of the indications, dosages, hazards, and precautions as set forth in the published literature. When using MUSTARGEN by the intracavitary route, the general precautions concerning this agent should be borne in mind. As a general guide, reference is made especially to the techniques of Weisberger et al. 5,11-13 Intracavitary use is indicated in the presence of pleural, peritoneal, or pericardial effusion due to metastatic tumors. Local therapy with nitrogen mustard is used only when malignant cells are demonstrated in the effusion. Intracavitary injection is not recommended when the accumulated fluid is chylous in nature, since results are likely to be poor. Paracentesis is first performed with most of the fluid being removed from the pleural or peritoneal cavity. The intracavitary use of MUSTARGEN may exert at least some of its effect through production of a chemical poudrage. Therefore, the removal of excess fluid allows the drug to more easily contact the peritoneal and pleural linings. For intrapleural or intrapericardial injection nitrogen mustard is introduced directly through the thoracentesis needle. For intraperitoneal injection it is given through a rubber catheter inserted into the trocar used for paracentesis or through a No.18 gauge needle inserted at another site. This drug should be injected slowly, with frequent aspiration to ensure that a free flow of fluid is present. If fluid cannot be aspirated, pain and necrosis due to injection of solution outside the cavity may occur. 5,11-13 Free flow of fluid also is necessary to prevent injection into a loculated pocket and to ensure adequate dissemination of nitrogen mustard. The usual dose of nitrogen mustard for intracavitary injection is 0.4 mg/kg of body weight, though 0.2 mg/kg (or 10 to 20 mg) has been used by the intrapericardial route. 5,11-13 The solution is prepared, as previously described for intravenous injection, by adding 10 mL of Sterile Water for Injection or 10 mL of Sodium Chloride Injection to the vial containing 10 mg of mechlorethamine hydrochloride. (Amounts of diluent of 50 to 100 mL of normal saline have also been used. 4,5) The position of the patient should be changed every 5 to 10 minutes for an hour after injection to obtain more uniform distribution of the drug throughout the serous cavity. The remaining fluid may be removed from the pleural or peritoneal cavity by paracentesis 24 to 36 hours later. The patient should be followed carefully by clinical and x-ray examination to detect reaccumulation of fluid. Pain occurs rarely with intrapleural use; it is common with intraperitoneal injection and is often associated with
nausea, vomiting, and diarrhea of 2 to 3 days duration. Transient cardiac irregularities may occur with intrapericardial injection. Death, possibly accelerated by nitrogen mustard, has been reported following the use of this agent by the intracavitary route. Although absorption of MUSTARGEN when given by the intracavitary route is probably not complete because of its rapid deactivation by body fluids, the systemic effect is unpredictable. The acute side effects such as nausea and vomiting are usually mild. Bone marrow depression is generally milder than when the drug is given intravenously. Care should be taken to avoid use by the intracavitary route when other agents which may suppress bone marrow function are being used systemically. Neutralization of Equipment and Unused Solution To clean rubber gloves, tubing, glassware, etc., after giving MUSTARGEN, soak them in an aqueous solution containing equal volumes of sodium thiosulfate (5%) and sodium bicarbonate (5%) for 45 minutes. Excess reagents and reaction products are washed away easily with water. Any unused injection solution should be neutralized by mixing with an equal volume of sodium thiosulfate/sodium bicarbonate solution. Allow the mixture to stand for 45 minutes. Vials that have contained MUSTARGEN should be treated in the same way with thiosulfate/bicarbonate solution before disposal.

How Supplied

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<td>No. 7753 — Trituration of MUSTARGEN is a light yellow brown crystalline powder, each vial containing 10 mg of mechlorethamine hydrochloride with sodium chloride q.s. 100 mg, and is supplied as follows: NDC 0006-7753-31 in treatment sets of 4 vials. Storage Store at controlled room temperature 15-30°C (59-86°F). Protect from light and humidity. Solutions of mechlorethamine HCl decompose on standing; therefore, solutions of the drug should be prepared immediately before use.</td>
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NDC 0006-7753-31

References


| Date | December 2002 |