



- Caregivers of children receiving Doxorubicin should take precautions (such as wearing latex gloves) to prevent contact with the patient's urine and other body fluids for at least 5 days after each treatment.

What should I avoid while taking Doxorubicin?

- Avoid receiving live vaccines during treatment with Doxorubicin. Talk to your doctor to find out which vaccines are safe for you while receiving Doxorubicin. See "What should I tell my doctor before receiving Doxorubicin?"

What are the possible side effects of Doxorubicin?

Doxorubicin can cause serious side effects including:

- See "What is the most important information I should know about Doxorubicin?"

Infusion site reactions. Serious infusion site reactions can happen with Doxorubicin. Symptoms of infusion reaction may include:

- pain at injection site
- skin redness or swelling
- burning or stinging
- open skin sores at injection site

Your doctor will watch you closely while you are receiving Doxorubicin and after your infusion for signs of a reaction. You may experience these reactions immediately or within 2 hours of infusion.

Change in the color of your urine. You may have red colored urine for 1 to 2 days after your infusion of Doxorubicin. This is normal. Tell your doctor if it does not stop in a few days, or if you see what looks like blood or blood clots in your urine.

Infection. Call your doctor right away if you get any of the following signs of infection:

- fever (temperature of 100.4 F or greater) chills or shivering
- cough that brings up mucus
- burning or pain with urination

Doxorubicin may cause lower sperm counts and sperm problems in men.

This could affect your ability to father a child and cause birth defects. Men should use effective birth control (contraception) while receiving Doxorubicin. Do not have unprotected sexual contact with a female who could become pregnant. Tell your doctor if you do have unprotected sexual contact with a female who could become pregnant. Talk to your doctor if this is a concern for you.

Irreversible amenorrhea or early menopause. Your periods (menstrual cycle) may completely stop when you receive Doxorubicin. Your periods may or may not return after you complete your treatment of Doxorubicin.

The most common side effects of Doxorubicin include:

- hair loss (alopecia). Your hair may re-grow after your treatment.
- darkening of your nails or separation of your nails from your nailbed
- nausea
- vomiting
- lack of appetite or increased thirst
- bruise or bleed more easily
- abnormal heart beat
- a secondary cancer may occur when Doxorubicin is combined with other chemotherapy agents.
- mouth sores
- weight changes
- stomach (abdominal) pain
- diarrhea
- eye problems
- allergic reactions. Call your doctor right away if you have any of the following symptoms of an allergic reaction:
 - rash
 - flushed face
 - fever
 - hives
 - dizziness or feel faint
 - itching
 - shortness of breath or trouble breathing
 - swelling of your lips or tongue

Tell your doctor or nurse if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Doxorubicin. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Doxorubicin.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

This leaflet summarizes the most important information about Doxorubicin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Doxorubicin that is written for healthcare professionals. For more information, call 1-800-521-5169.

What are the ingredients of Doxorubicin?

Active ingredient: Doxorubicin hydrochloride

Inactive ingredient: lactose monohydrate, sodium chloride 0.9%, water for injection, and hydrochloric acid.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Bedford Laboratories™
Bedford, OH 44146
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Extravasation

On intravenous administration of doxorubicin, extravasation may occur with or without an accompanying stinging or burning sensation, even if blood returns well on aspiration of the infusion needle. If any signs or symptoms of extravasation have occurred, the injection or infusion should be immediately terminated and restarted in another vein (see **DOSAGE AND ADMINISTRATION**).

Hepatic Impairment

Since metabolism and excretion of doxorubicin occurs predominantly by the hepatobiliary route, toxicity of recommended doses of doxorubicin can be enhanced by hepatic impairment; therefore, prior to individual dosing, evaluation of hepatic function is recommended using conventional laboratory tests such as SGOT, SGPT, alkaline phosphatase, and bilirubin (see **DOSAGE AND ADMINISTRATION**).

Immunosuppressant Effects/Increased Susceptibility to Infections

Administration of live or live-attenuated vaccines in patients immunocompromised by chemotherapeutic agents including doxorubicin, may result in serious or fatal infections. Vaccination with a live vaccine should be avoided in patients receiving doxorubicin. Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.

Pregnancy Category D

Doxorubicin can cause fetal harm when administered to a pregnant woman. Doxorubicin was teratogenic and embryotoxic at doses of 0.8 mg/kg/day (about 1/13 the recommended human dose on a body surface area basis) when administered during the period of organogenesis in rats. Teratogenicity and embryotoxicity were also seen using discrete periods of treatment. The most susceptible was the 6- to 9-day gestation period at doses of 1.25 mg/kg/day and greater. Characteristic malformations included esophageal and intestinal atresia, tracheo-esophageal fistula, hypoplasia of the urinary bladder and cardiovascular anomalies. Doxorubicin was embryotoxic (increase in embryofetal deaths) and abortifacient at 0.4 mg/kg/day (about 1/14 the recommended human dose on a body surface area basis) in rabbits when administered during the period of organogenesis.

There are no adequate and well-controlled studies in pregnant women. If doxorubicin is to be used during pregnancy, or if the patient becomes pregnant during therapy, the patient should be apprised of the potential hazard to the fetus. Women of childbearing age should be advised to avoid becoming pregnant.

PRECAUTIONS

General

Doxorubicin is not an anti-microbial agent. Doxorubicin is emetogenic. Antiemetics may reduce nausea and vomiting; prophylactic use of antiemetics should be considered before administration of doxorubicin, particularly when given in conjunction with other emetogenic drugs. Doxorubicin should not be administered in combination with other cardiotoxic agents unless the patient's cardiac function is closely monitored. Patients receiving doxorubicin after stopping treatment with other cardiotoxic agents, especially those with long half-lives such as trastuzumab, may also be at an increased risk of developing cardiotoxicity. Physicians should avoid doxorubicin-based therapy for up to 24 weeks after stopping trastuzumab when possible. If doxorubicin used before this time, careful monitoring of cardiac function is recommended (See **WARNINGS, DOSAGE AND ADMINISTRATION**).

Information for Patients

Patients should be informed of the expected adverse effects of doxorubicin, including gastrointestinal symptoms (nausea, vomiting, diarrhea, and stomatitis) and potential neutropenic complications. Patients should consult their physician if vomiting, dehydration, fever, evidence of infection, symptoms of CHF, or injection-site pain occurs following therapy with doxorubicin. Patients should be informed that they will almost certainly develop alopecia. Patients should be advised that their urine may appear red for 1 to 2 days after administration of doxorubicin and that they should not be alarmed. Patients should understand that there is a risk of irreversible myocardial damage associated with treatment with doxorubicin, as well as a risk of treatment-related leukemia. Because doxorubicin may induce chromosomal damage in sperm, men undergoing treatment with doxorubicin should use effective contraceptive methods. Women treated with doxorubicin may develop irreversible amenorrhea, or premature menopause.

Drug Interactions

Doxorubicin is extensively metabolized by the liver. Changes in hepatic function induced by concomitant therapies may affect doxorubicin metabolism, pharmacokinetics, therapeutic efficacy, and/or toxicity. Toxicities associated with doxorubicin, especially hematologic and gastrointestinal events, may be increased when doxorubicin is used in combination with other cytotoxic drugs.

Pacitaxel: There have been a number of reports in the literature that describe an increase in cardiotoxicity when doxorubicin is co-administered with paclitaxel. Two published studies report that initial administration of paclitaxel infused over 24 hours followed by doxorubicin administered over 48 hours resulted in a significant decrease in doxorubicin clearance with more profound neutropenic and stomatitis episodes than the reverse sequence of administration.

Progesterone: In a published study, progesterone was given intravenously to patients with advanced malignancies (ECOG PS < 2) at high doses (up to 10 g over 24 hours) concomitantly with a fixed doxorubicin dose (60 mg/m²) via bolus injection. Enhanced doxorubicin-induced neutropenia and thrombocytopenia were observed.

Verapamil: A study of the effects of verapamil on the acute toxicity of doxorubicin in mice revealed higher initial peak concentrations of doxorubicin in the heart with a higher incidence and severity of degenerative changes in cardiac tissue resulting in a shorter survival.

Cyclosporine: The addition of cyclosporine to doxorubicin may result in increases in AUC for both doxorubicin and doxorubicinol possibly due to a decrease in clearance of parent drug and a decrease in metabolism of doxorubicinol. Literature reports suggest that adding cyclosporine to doxorubicin results in more profound and prolonged hematologic toxicity than doxorubicin alone. Coma and/or seizures have also been described.

Dexrazoxane: In a clinical study of women with metastatic breast cancer, the concurrent use of the cardioprotectant, dexrazoxane, with the initiation of a regimen of fluorouracil, doxorubicin, and cyclophosphamide (FAC) was associated with a lower tumor response rate. Later initiation of dexrazoxane (after administration of a cumulative doxorubicin dose of 300 mg/m² of doxorubicin had been given as a component of FAC) was not associated with a reduction in chemotherapy activity. Dexrazoxane is only indicated for use in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m² and are continuing with doxorubicin therapy.

Cytarabine: Necrotizing colitis manifested by typhilitis (cecal inflammation), bloody stools and severe and sometimes fatal infections have been associated with a combination of doxorubicin given by intravenous push daily for 3 days and cytarabine given by continuous infusion daily for 7 or more days.

Sorafenib: In clinical studies, both an increase of 21% and 47%, and no change in the AUC of doxorubicin were observed with concomitant treatment with sorafenib 400 mg twice daily. The clinical significance of these findings is unknown.

Cyclophosphamide: The addition of cyclophosphamide to doxorubicin treatment does not affect exposure to doxorubicin, but may result in an increase in exposure to doxorubicinol, a metabolite. Doxorubicinol only has 5% of the cytotoxic activity of doxorubicin. Concurrent treatment with doxorubicin has been reported to exacerbate cyclophosphamide-induced hemorrhagic cystitis. Acute myeloid leukemia has been reported as a second malignancy after treatment with doxorubicin and cyclophosphamide.

Literature reports have also described the following drug interactions: Phenobarbital increases the elimination of doxorubicin; phenytoin levels may be decreased by doxorubicin; streptozocin (Zanosar®) may inhibit hepatic metabolism of doxorubicin; saquinavir in combination with cyclophosphamide, doxorubicin, and etoposide increased mucosal toxicity in patients with HIV-associated non-Hodgkin's lymphoma; and administration of live vaccines to immunosuppressed patients including those undergoing cytotoxic chemotherapy may be hazardous (see **WARNINGS**).

Laboratory Tests

Initial treatment with doxorubicin requires observation of the patient and periodic monitoring of complete blood counts, hepatic function tests, and left ventricular ejection fraction (see **WARNINGS**). Abnormalities of hepatic function tests may occur. Like other cytotoxic drugs, doxorubicin may induce "tumor lysis syndrome" and hyperuricemia in patients with rapidly growing tumors. Blood uric acid levels, potassium, calcium, phosphate, and creatinine should be evaluated after initial treatment. Hydration, urine alkalinization, and prophylaxis with allopurinol to prevent hyperuricemia may minimize potential complications of tumor-lysis syndrome.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenicity studies have not been conducted with doxorubicin. Secondary acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS) have been reported in patients treated with doxorubicin-containing combination chemotherapy regimens (see **WARNINGS**). Pediatric patients treated with doxorubicin or other topoisomerase II inhibitors are at risk for developing acute myelogenous leukemia and other neoplasms. Doxorubicin was mutagenic in the *in vitro* Ames assay, and clastogenic in multiple *in vitro* assays (CHO cell, V79 hamster cell, human lymphoblast, and SCE assays) and the *in vivo* mouse micronucleus assay.

Doxorubicin decreased fertility in female rats at the doses of 0.05 and 0.2 mg/kg/day (about 1/200 and 1/50 the recommended human dose on a body surface area basis) when administered from 14 days before mating late gestation period. A single IV dose of doxorubicin at 0.1 mg/kg (about 1/100 the recommended human dose on a body surface area basis) was toxic to male reproductive organs producing testicular atrophy and oligospermia in rats. Doxorubicin is mutagenic as it induced DNA damage in rabbit spermatozoa and dominant lethal mutations in mice. Therefore, doxorubicin may potentially induce chromosomal damage in human spermatozoa. Oligospermia or azoospermia were evidenced in men treated with doxorubicin, mainly in combination therapies. Men undergoing doxorubicin treatment should use effective contraceptive methods.

Doxorubicin was toxic to male reproductive organs in animal studies, producing testicular atrophy, diffuse degeneration of the seminiferous tubules, and hypospermia. Doxorubicin is mutagenic as it induces DNA damage in rabbit spermatozoa and dominant lethal mutations in mice. Therefore, doxorubicin can potentially induce chromosomal damage in human spermatozoa. Oligospermia or azoospermia were evidenced in men treated with doxorubicin, mainly in combination therapies. This effect may be permanent. However, sperm counts have been reported to return to normal levels in some instances. This may occur several years after the end of therapy. Men undergoing doxorubicin treatment should use effective contraceptive methods.

In women, doxorubicin may cause infertility during the time of drug administration. Doxorubicin may cause amenorrhea. Ovulation and menstruation may return after termination of therapy, although premature menopause can occur. Recovery of menses is related to age at treatment.

Secondary acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS) have been reported in patients treated with anthracycline-containing adjuvant combination chemotherapy regimens (see **WARNINGS, Hematologic Toxicity**).

Pregnancy: Teratogenic Effects; Pregnancy Category D

(See **WARNINGS**.)

Nursing Mothers

Doxorubicin and its major metabolite, doxorubicinol, have been detected in the milk of at least one lactating patient (see **CLINICAL PHARMACOLOGY, Pharmacokinetics**). Because of the potential for serious adverse reactions in nursing infants from doxorubicin, mothers should be advised to discontinue nursing during doxorubicin therapy.

Pediatric Use

Pediatric patients are at increased risk for developing delayed cardiotoxicity. Follow-up cardiac evaluations are recommended periodically to monitor for this delayed cardiotoxicity (see **WARNINGS**). Doxorubicin, as a component of intensive chemotherapy regimens administered to pediatric patients, may contribute to prepubertal growth failure. It may also contribute to gonadal impairment, which is usually temporary. Pediatric patients treated with doxorubicin or other topoisomerase II inhibitors are at risk for developing acute myelogenous leukemia and other neoplasms. Pediatric patients receiving concomitant doxorubicin and actinomycin-D have manifested acute "recall" pneumonitis at variable times after local radiation therapy.

Geriatric Use

An estimated 4600 patients who were 65 and over were included in the reported clinical experience of doxorubicin use for various indications. No overall differences in safety and effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. The decision to use doxorubicin in the treatment of older patients should be based upon a consideration of overall performance status and concurrent illnesses, in addition to age of the individual patient.

ADVERSE REACTIONS

Dose limiting toxicities of therapy are myelosuppression and cardiotoxicity. Other reactions reported are:

Cardiotoxicity -- (See **WARNINGS**.)

Cutaneous -- Reversible complete alopecia occurs in most cases. Hyperpigmentation of nailbeds and dermal creases, primarily in pediatric patients, and onycholysis have been reported in a few cases. Radiation recall reaction has occurred with doxorubicin administration. Rash, itching, or photosensitivity may occur.

Gastrointestinal -- Acute nausea and vomiting occurs frequently and may be severe. This may be alleviated by antiemetic therapy. Mucositis (stomatitis and esophagitis) may occur within 5 to 10 days of beginning therapy, and most patients recover from this adverse event within another 5 to 10 days. The effect may be severe leading to ulceration and represents a site of origin for severe infections. The dosage regimen consisting of administration of doxorubicin on three successive days results in greater incidence and severity of mucositis. Ulceration and necrosis of the colon, especially the cecum, may occur leading to bleeding or severe infections which can be fatal. This reaction has been reported in patients with acute non-lymphocytic leukemia treated with a 3-day course of doxorubicin combined with cytarabine. Anorexia, abdominal pain, dehydration, diarrhea, and hyperpigmentation of the oral mucosa have been occasionally reported.

Hematologic -- (See **WARNINGS**.)

Hypersensitivity -- Fever, chills, and urticaria have been reported occasionally. Anaphylaxis may occur. A case of apparent cross sensitivity to lincomycin has been reported.

Neurological -- Peripheral neurotoxicity in the form of local-regional sensory and/or motor disturbances have been reported in patients treated intra-arterially with doxorubicin, mostly in combination with cisplatin. Animal studies have demonstrated seizures and coma in rodents and dogs treated with intra-carotid doxorubicin. Seizures and coma have been reported in patients treated with doxorubicin in combination with cisplatin or vincristine.

Ocular -- Conjunctivitis, keratitis, and lacrimation occur rarely.

Other -- Malaise/asthenia have been reported.

Adverse Reactions in Patients with Early Breast Cancer Receiving Doxorubicin-Containing Adjuvant Therapy: Safety data were collected from approximately 2300 women who participated in a randomized, open-label trial (NSABP B-15) evaluating the use of AC versus CMF in the treatment of early breast cancer involving axillary lymph nodes. In the safety analysis, the follow-up data from all patients receiving AC were combined (N=1492 evaluable patients) and compared with data from patients receiving conventional CMF (i.e., oral cyclophosphamide; N=739 evaluable patients). The most relevant adverse events reported in this study are provided in Table 2.

Table 2. Relevant Adverse Events in Patients with Early Breast Cancer Involving Axillary Lymph Nodes

	AC*	Coneventional CMF
	N=1492	N=739
Treatment administration		
Mean number of cycles	3.8	5.5
Total cycles	5676	4068
Adverse events, % of patients		
Leukopenia		
Grade 3 (1,000-1,999/mm ³)	3.4	9.4
Grade 4 (<1000/mm ³)	0.3	0.3
Thrombocytopenia		
Grade 3 (25,000-49,999/mm ³)	0	0.3
Grade 4 (<25,000/mm ³)	0.1	0
Shock, sepsis	1.5	0.9
Systemic infection	2.4	1.2
Nausea and vomiting		
Nausea only	15.5	42.8
Vomiting ≤12 hours	34.4	25.2
Vomiting >12 hours	36.8	12.0
Intractable	4.7	1.6
Alopecia		
Partial	92.4	71.4
Complete	22.9	56.3
	69.5	15.1
Weight loss		
5-10%	6.2	5.7
>10%	2.4	2.8
Weight loss		
5-10%	10.6	27.9
>10%	3.8	14.3
Cardiac function		
Asymptomatic	0.2	0.1
Transient	0.1	0
Symptomatic	0.1	0
Treatment-related death	0	0

* Includes pooled data from patients who received either AC alone for 4 cycles, or who were treated with AC for 4 cycles followed by 3 cycles of CMF

OVERDOSAGE

Acute overdosage with doxorubicin enhances the toxic effects of mucositis, leukopenia, and thrombocytopenia. Treatment of acute overdosage consists of treatment of the severely myelosuppressed patient with hospitalization, antimicrobials, platelet transfusions and symptomatic treatment of mucositis. Use of hemopoietic growth factor (G-CSF, GM-CSF) may be considered.

The 200 mg Adriamycin (DOXOrubicin HCl) Injection, USP is packaged as a multiple dose vial and caution should be exercised to prevent inadvertent overdosage.

Cumulative dosage with doxorubicin increases the risk of cardiomyopathy and resultant congestive heart failure (see **WARNINGS**). Treatment consists of vigorous management of congestive heart failure with digitalis preparations, diuretics, and after-load reducers such as ACE inhibitors.

DOSAGE AND ADMINISTRATION

When possible, to reduce the risk of developing cardiotoxicity in patients receiving doxorubicin after stopping treatment with other cardiotoxic agents, especially those with long half-lives such as trastuzumab, doxorubicin-based therapy should be delayed until the other agents have cleared from the circulation (See **WARNINGS** and **PRECAUTIONS, General**).

Care in the administration of doxorubicin will reduce the chance of perivenous infiltration (see **WARNINGS**). It may also decrease the chance of local reactions such as urticaria and erythematous streaking. On intravenous administration of doxorubicin, extravasation may occur with or without an accompanying burning or stinging sensation, even if blood returns well on aspiration of the infusion needle. If any signs or symptoms of extravasation have occurred, the injection or infusion should be immediately terminated and restarted in another vein. If extravasation is suspected, intermittent application of ice to the site for 15 min. q.i.d. x 3 days may be useful. The benefit of local administration of drugs has not been clearly established. Because of the progressive nature of extravasation reactions, close observation and plastic surgery consultation are recommended. Blistering, ulceration and/or persistent pain are indications for wide excision surgery, followed by split-thickness skin grafting.

The most commonly used dose schedule when used as a single agent is 60 to 75 mg/m² as a single intravenous injection administered at 21-day intervals. The lower dosage should be given to patients with inadequate marrow reserves due to old age, or prior therapy, or neoplastic marrow infiltration.



Doxorubicin has been used concurrently with other approved chemotherapeutic agents. Evidence is available that in some types of neoplastic disease, combination chemotherapy is superior to single agents. The benefits and risks of such therapy continue to be elucidated. When used in combination with other chemotherapy drugs, the most commonly used dosage of doxorubicin is 40 to 60 mg/m² given as a single intravenous injection every 21 to 28 days.

In a large randomized study (NSABP B-15) of patients with early breast cancer involving axillary lymph nodes (see **CLINICAL PHARMACOLOGY, Clinical Studies and ADVERSE REACTIONS, Adverse Reactions in Patients with Early Breast Cancer Receiving Doxorubicin-Containing Adjuvant Therapy**), the combination dosage regimen of AC (doxorubicin 60 mg/m² and cyclophosphamide 600 mg/m²) was administered intravenously on day 1 of each 21-day treatment cycle. Four cycles of treatment were administered.

Dose Modifications

Patients in the NSABP B-15 study could have dose modifications of AC to 75% of the starting doses for neutropenic fever/infection. When necessary, the next cycle of treatment cycle was delayed until the absolute neutrophil count (ANC) was ≥1000 cells/mm³ and the platelet count was ≥100,000 cells/mm³ and nonhematologic toxicities had resolved.

Doxorubicin dosage must be reduced in case of hyperbilirubinemia as follows:

Plasma bilirubin concentration (mg/dL)	Dosage reduction (%)
1.2–3.0	50
3.1–5.0	75

Reconstitution Directions

It is recommended that doxorubicin be slowly administered into the tubing of a freely running intravenous infusion of Sodium Chloride Injection or 5% Dextrose Injection. The tubing should be attached to a Butterfly® needle inserted preferably into a large vein. If possible, avoid veins over joints or in extremities with compromised venous or lymphatic drainage. The rate of administration is dependent on the size of the vein and the dosage. However, the dose should be administered in not less than 3 to 5 minutes. Local erythematous streaking along the vein as well as facial flushing may be indicative of too rapid an administration. A burning or stinging sensation may be indicative of perivenous infiltration and, if this occurs, the infusion should be immediately terminated and restarted in another vein. Perivenous infiltration may occur painlessly.

Doxorubicin should not be mixed with heparin or fluorouracil since it has been reported that these drugs are incompatible to the extent that a precipitate may form. Contact with alkaline solutions should be avoided since this can lead to hydrolysis of doxorubicin. Until specific compatibility data are available, it is not recommended that doxorubicin be mixed with other drugs.

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

Handling and Disposal

Procedures for proper handling and disposal of anti-cancer drugs should be considered. Several guidelines on this subject have been published. 1-4 There is no general agreement that all the procedures recommended in the guidelines are necessary or appropriate. However, given the toxic nature of this substance, the following protective recommendations are provided:

- Personnel should be trained in good technique for reconstitution and handling.
- Pregnant staff should be excluded from working with this drug.
- Personnel handling doxorubicin should wear protective clothing: goggles, gowns, and disposable gloves and masks.
- A designated area should be defined for reconstitution (preferably under a laminar flow system). The work surface should be protected by disposable, plastic-backed, absorbent paper.
- All items used for reconstitution, administration or cleaning, including gloves, should be placed in high-risk waste-disposal bags for high-temperature incineration.
- Spillage or leakage should be treated with dilute sodium hypochlorite (1% available chlorine) solution, preferably by soaking, and then water.
- All cleaning materials should be disposed of as indicated previously.
- In case of skin contact, thoroughly wash the affected area with soap and water or sodium bicarbonate solution. However, do not abrade the skin by using a scrub brush.
- In case of contact with the eye(s), hold back the eyelid(s) and flush the affected eye(s) with copious amounts of water for at least 15 minutes. Then seek medical evaluation by a physician.
- Always wash hands after removing gloves.

Caregivers of pediatric patients receiving doxorubicin should be counseled to take precautions (such as wearing latex gloves) to prevent contact with the patient's urine and other body fluids for at least 5 days after each treatment.

HOW SUPPLIED

Adriamycin (DOXOrubicin HCl) for Injection, USP is supplied as a sterile red-orange lyophilized powder in single dose flip-top vials in the following package strengths:

NDC 55390-231-10: 10 mg vial; carton of 10.

NDC 55390-232-10: 20 mg vial; carton of 10.

NDC 55390-233-01: 50 mg vial; individually boxed.

Store unconstituted vial at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. **Protect from light.** Retain in carton until time of use. Discard unused portion.

Reconstituted Solution Stability

After adding the diluent, the vial should be shaken and the contents allowed to dissolve. The reconstituted solution is stable for 7 days at room temperature and under normal room light (100 foot-candles) and 15 days under refrigeration (2° to 8°C). It should be protected from exposure to sunlight. Discard any unused solution from the 10 mg, 20 mg and 50 mg single dose vials.

Adriamycin (DOXOrubicin HCl) Injection, USP is supplied in single-dose, flip-top vials, as a red-orange solution containing Doxorubicin Hydrochloride, USP 2 mg/mL in the following package strengths:

NDC 55390-235-10: 10 mg in 5 mL; carton of 10.

NDC 55390-236-10: 20 mg in 10 mL; carton of 10.

NDC 55390-237-01: 50 mg in 25 mL; individually boxed.

Store refrigerated, 2° to 8°C (36° to 46°F).

Protect from light. Retain in carton until time of use. Discard unused portion.

Adriamycin (DOXOrubicin HCl) Injection, USP is supplied in a sterile, multiple dose, flip-top vial, as a red-orange solution containing Doxorubicin Hydrochloride, USP 2 mg/mL in the following package strength:

NDC 55390-238-01: 200 mg in 100 mL; individually boxed.

Store refrigerated, 2° to 8°C (36° to 46°F).

Protect from light. Retain in carton until contents are used.

REFERENCES