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1 ANTI GRANULOCYTE COLONY STIMULATING ACTIVITY
2 HUMAN ALPHA 2 MACROGLOBULIN
3 HUMAN ALPHA 1 ANTITRYPSIN
4 HUMAN CERULOPLASMIN
5 CYTOCHROM C
6 HUMAN HEMOGLOBIN
7 HUMAN GAMMA GLOBULIN
8 OVALBUMIN
9 POOLED NORMAL HUMAN SERUM
10 HUMAN MYOLOBIN
11 HUMAN TRANSFERRIN
12 CHYMOTRYPSINOGEN A
13 Zs ALFA 2 GLYCOPROTEIN
14 HUMAN BET2 2 GLYCOPROTEIN II

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**VOLUME 4**

Edited by THEODORE H. SPAET, M.D.


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Faculty: David Baltimore, Ph.D., Paul Chervenick, M.D., Robert Gallo, M.D., Ronald McCaffrey, M.D., Donald Pinkel, M.D., Janet Rowley, M.D., Howard Weinstein, M.D., Peter Wiernick, M.D., and Warren Winkelstein, M.D.

For further information contact: Ms. Bernadette Stohlman, St. Elizabeth's Hospital, Box 100, 730 Cambridge Street, Brighton, Mass. 02135. Tel.: 617 782-7000, ext. 707.
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<th>In 5 ml Vials</th>
<th>In Bags</th>
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<tbody>
<tr>
<td>Factor VII, XI, XII</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 ml</td>
<td>$50.00</td>
<td>250 ml</td>
</tr>
<tr>
<td>25 ml</td>
<td>100.00</td>
<td>500 ml</td>
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<tr>
<td>50 ml</td>
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<td>1000 ml</td>
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<tr>
<td>100 ml</td>
<td>320.00</td>
<td></td>
</tr>
<tr>
<td>Factor VIII</td>
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<tr>
<td>10 ml</td>
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<tr>
<td>25 ml</td>
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<td>500 ml</td>
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<tr>
<td>50 ml</td>
<td>115.00</td>
<td>1000 ml</td>
</tr>
<tr>
<td>100 ml</td>
<td>140.00</td>
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Severe local tissue necrosis will occur if there is extravasation during administration.

Severe irreversible myocardial toxicity with delayed congestive failure often unresponsive to any cardiac supportive therapy may be encountered as total dosage approaches 550 mg/m². This toxicity may occur at lower cumulative doses in patients with prior mediastinal irradiation or on concurrent cyclophosphamide therapy.

The incidence of bone marrow depression is high. Hematopoietic toxicity may limit dosage.

In patients with impaired hepatic function, dosage should be reduced.

For information on the use of Adriamycin, call collect: (614) 889-1300.

(Photomicrographs courtesy of Dr. J.E. Ullmann and Dr. R.S. Stein)

### Adriamycin™ (doxorubicin hydrochloride) for Injection

FOR INTRAVENOUS USE ONLY

10 mg and 50 mg vials

For complete prescribing information, please see the following page.
Use in Pregnancy—Safe use of Adriamycin in pregnancy has not been established. Adriamycin is embryotoxic and teratogenic in rats and embryotoxic and abortifacient in rabbits. Therefore the benefits to the pregnant patient should be carefully weighed against the potential toxicity to fetus and embryo. The possible adverse effects on fertility in males and females in humans or experimental animals have not been adequately evaluated.

Precautions
Internal treatment with Adriamycin requires close observation of the patient and extensive laboratory monitoring. It is recommended, therefore, that patients be hospitalized at least during the first phase of the treatment.

Other cytostatic drugs. Adriamycin may induce hyperuricaemia secondary to rapid loss of neoplastic cells. The clinician should monitor the patient’s blood urea and acid level and be prepared to use such supportive and pharmacologic measures as might be necessary to control this problem.

Adriamycin imparts a red coloration to the urine for 1-2 days after administration and patients should be advised to expect this during active therapy. Adriamycin is not an anti-microbial agent.

ADVERSE REACTIONS
Dose limiting toxicities of therapy are myelosuppression and cardiotoxicity (see Warnings). Other reactions reported are:

Gastrointestinal—Acute nausea and vomiting occurs frequently and may be severe. This may be alleviated by antemiotic therapy. Mucositis (stomatitis and esophagitis) may occur 5-10 days after administration. The effect may be severe leading to ulceration and represent a site of origin for severe septicemia. The dose regimen consisting of administration of Adriamycin on three successive days results in the greater incidence and severity of mucositis. Anorexia and diarrhea have been occasionally reported.

Venous—Phlebitis has been reported especially when small veins are used or a single venp is used for repeated administration. Facial flushing may occur if the injection is given too rapidly.

Cardiac—Severe cellulositis, reteation and tissue necrosis will occur if Adriamycin is administrated during erythromelalgia. Staining streaming along the vein proximal to the site of the injection has been reported.

Hypersensitivity—Fever, chills, urticaria and hives have been reported occasionally. Anaphylaxis may occur.

A case of apparent cross sensitivity to thioridazine has been reported.

DOSAGE AND ADMINISTRATION
Care in the administration of Adriamycin will reduce the chance of perivascular infiltration. It may also decrease the chance of local reactions such as erythema and erythromelalgia, streaming.

The recommended dosage schedule is 50-75 mg/m2 as a single intravenous injection administered at 21-day intervals. The lower dose should be given to patients with inadequate marrow reserves due to old age or prior therapy, or those receiving concomitant dose-sparing drugs. The recommended dose schedule is 30 mg/m2 on each of the three successive days repeated every 4 weeks. Adriamycin dosage must be reduced if hepatic function is impaired according to the following table:

<table>
<thead>
<tr>
<th>Serum Bicarbonate</th>
<th>BSP Retention</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.0-20.0 mEq/L</td>
<td>9-15%</td>
<td>1/4 normal dose</td>
</tr>
<tr>
<td>3-6 mEq/L</td>
<td>15%</td>
<td>1/8 normal dose</td>
</tr>
</tbody>
</table>

Preparation of Solution: Adriamycin 10 mg vials and 50 mg vials should be reconstituted with 5 ml and 25 ml respectively of Sodium Chloride Injection U.S.P. to give a final concentration of 2 mg/ml of doxorubicin hydrochloride. An appropriate volume of air should be withdrawn from the vial during reconstitution to avoid excessive pressure build-up.

Skin reactions associated with Adriamycin have been reported. Caution in the handling and preparation of the powder and solution must be exercised and the use of gloves is recommended. If Adriamycin powder or solution contacts the skin or mucous immediately wash thoroughly with soap and water.

After the injection, the site should be watched and the patients allowed to disrobe. The reconstituted solution is stable for 24 hours at room temperature and 48 hours under refrigeration (4-10°C). It should be protected from exposure to sunlight and any unused solution should be discarded.

It is recommended that Adriamycin be slowly administered into the tubing of a freely running intravenous infusion of Sodium Chloride Injection U.S.P. or 5% Dextrose Injection U.S.P. The tubing should be attached to a butterfly needle inserted preferentially into a large vein. The rate of administration is dependent on the size of the vein and the dosage; however, the dose should be administered not more than 3 to 5 minutes. Local erythromelalgia streaming along the vein as well as facial flushing may be indicative of too rapid an administration. A turning or stringing sensation may be indicative of perivascular infiltration and the infusion should be immediately terminated and restarted in another vein.

Adriamycin should not be mixed with heparin since it has been reported that these drugs are incompatible to the extent that a precipitate may form. Unlike specific compatibility data are available, it is not recommended that Adriamycin be mixed with other drugs.

Adriamycin has been used in combination with other approved chemotherapeutic agents. Though evidence is available that at least in some types of neoplastic disease combination chemotherapy is superior to single agents, the benefits and risks of such therapy have not yet been fully elucidated.
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