DOXOrubicin

HCl Injection, USP

50 mg per 25 mL | NDC 70860-208-25

200 mg per 100 mL | NDC 70860-208-51

- **ATHENEX AccuraSEE℠ PACKAGING AND LABELING**
- **BIG, BOLD AND BRIGHT —
  TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT**
- **DIFFERENTIATION IN EVERY LABEL,
  DESIGNED TO HELP REDUCE MEDICATION ERRORS**

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR DOXORUBICIN HCl INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

DOXOrubicin

HCl Injection, USP

50 mg

NDC 70860-208-25

50 mg per 25 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

200 mg

NDC 70860-208-51

200 mg per 100 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

AccuraSEE℠ PACKAGING & LABELING

CHOOSE AccuraSEE℠ FOR YOUR PHARMACY

Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

With a unique AccuraSEE label design for every Athenex product, we're helping your pharmacy to reduce the risk of medication errors. The idea is simple: "So what you see is *exactly* what you get."

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DOXORUBICIN HYDROCHLORIDE Injection

INDICATIONS AND USAGE

- Doxorubicin Hydrochloride (HCl) Injection is indicated as a component of multiagent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer.
- Doxorubicin HCl is indicated for the treatment of: acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, Non-Hodgkin lymphoma, metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcomas, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, metastatic bronchogenic carcinoma.

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOMYOPATHY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION

- **Cardiomyopathy: Myocardial damage, including acute left ventricular failure can occur with doxorubicin HCl. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 1% to 20% for cumulative doses ranging from 300 mg/m² to 500 mg/m² when doxorubicin HCl is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess LVEF before and regularly during and after treatment with doxorubicin HCl.**
- **Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including doxorubicin HCl.**
- **Extravasation and Tissue Necrosis: Extravasation of doxorubicin HCl can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area.**
- **Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur.**

CONTRAINDICATIONS

- Doxorubicin HCl is contraindicated in patients with severe myocardial insufficiency.
- Doxorubicin HCl is contraindicated in patients with recent (occurring within the past 4 to 6 weeks) myocardial infarction.
- Doxorubicin HCl is contraindicated in patients with severe persistent drug-induced myelosuppression.
- Doxorubicin HCl is contraindicated in patients with severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin level greater than 5 mg/dL).
- Doxorubicin HCl is contraindicated in patients with severe hypersensitivity reaction to doxorubicin HCl including anaphylaxis.

WARNINGS AND PRECAUTIONS

- Doxorubicin HCl can result in myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy is generally proportional to the cumulative exposure. Include prior doses of other anthracyclines or anthracenediones in calculations of total cumulative dosage for doxorubicin HCl. Cardiomyopathy may develop during treatment or up to several years after completion of treatment and can include decrease in left ventricular ejection fraction (LVEF) and signs and symptoms of congestive heart failure (CHF). There is an additive or potentially synergistic increase in the risk of cardiomyopathy in patients who have received radiotherapy to the mediastinum or concomitant therapy with other known cardiotoxic agents such as cyclophosphamide and trastuzumab.
- Pericarditis and myocarditis have been reported during or following doxorubicin HCl treatment. Assess left ventricular function prior to initiation of doxorubicin HCl, during treatment to detect acute changes, and after treatment to detect delayed cardiotoxicity. Consider the use of dexrazoxane to reduce the incidence and severity of cardiomyopathy due to doxorubicin HCl administration in patients who have received a cumulative doxorubicin HCl dose of 300 mg/m² and who will continue to receive doxorubicin HCl.
- Doxorubicin HCl can result in arrhythmias, including life-threatening arrhythmias, during or within a few hours after doxorubicin HCl administration and at any time point during treatment.
- The risk of developing secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) is increased following treatment with doxorubicin HCl.
- Extravasation of doxorubicin HCl can result in severe local tissue injury manifesting as blistering, ulceration, and necrosis requiring wide excision of the affected area and skin grafting. When given via a peripheral venous line, infuse doxorubicin over 10 minutes or less to minimize the risk of thrombosis or perivenous extravasation. If extravasation is suspected, apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. If appropriate, administer dexrazoxane at the site of extravasation as soon as possible and within the first 6 hours after extravasation.
- Doxorubicin HCl can cause myelosuppression. Obtain baseline assessment of blood counts and carefully monitor patients during treatment for possible clinical complications due to myelosuppression.
- The clearance of doxorubicin is decreased in patients with elevated serum bilirubin with an increased risk of toxicity. Reduce the dose of doxorubicin HCl in patients with serum bilirubin levels of 1.2 to 5.0 mg/dL. Obtain liver tests including SGOT, SGPT, alkaline phosphatase, and bilirubin prior to and during doxorubicin HCl therapy.
- Doxorubicin HCl may induce tumor lysis syndrome in patients with rapidly growing tumors. Evaluate blood uric acid levels, potassium, calcium, phosphate, and creatinine after initial treatment. Hydration, urine alkalinization, and prophylaxis with allopurinol to prevent hyperuricemia may minimize potential complications of tumor lysis syndrome.
- Doxorubicin HCl can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive doxorubicin HCl after prior radiation therapy.
- Doxorubicin HCl can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus. Advise female patients of reproductive potential to use highly effective contraception during treatment with doxorubicin HCl and for 6 months after treatment. Advise patients to contact their healthcare provider if they become pregnant, or if pregnancy is suspected, while taking doxorubicin HCl.
- Doxorubicin HCl may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Males with female sexual partners of reproductive potential should use effective contraception during and for 6 months after treatment
- Because of the potential for serious adverse reactions in nursing infants from doxorubicin HCl, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- In females of reproductive potential, doxorubicin HCl may cause infertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment.
- In males, doxorubicin HCl may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men. This may occur several years after the end of therapy.

ADVERSE REACTIONS

- The most common (>10%) adverse drug reactions are alopecia, nausea, and vomiting.

OVERDOSAGE

- Few cases of overdose have been described. Acute overdosage with doxorubicin enhances the toxic effect 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for DOXORUBICIN HYDROCHLORIDE Injection.