WARNINGS

1. Do not administer to patients who are hypersensitive to doxorubicin, any of its excipients, or other anthracyclines or anthracenediones. (See CONTRAINDICATIONS.)

2. Use only under the supervision of a physician experienced in the use of cancer chemotherapeutic agents.

ADDITIONAL INFORMATION

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containing anthracyclines (including doxorubicin) and DNA-damaging antineoplastic agents, in combination with radiotherapy, the occurrence of secondary AML or MDS has been reported most commonly in patients treated with chemotherapy regimens containing cyclophosphamide and doxorubicin (anthracyclines) and ifosfamide (DNA-damaging agents) (see CONTRAINDICATIONS). calendar doses of doxorubicin may vary depending on the schedule and route of administration used. For example, the M.D. Anderson Cancer Center recommends that doxorubicin be given at a dose of 45 mg/m2 over 1 hour every 3 weeks for patients with breast cancer. The recommended dose for doxorubicin is 50 mg/m2 given over 1 hour monthly for patients with certain types of solid tumors.

ADVERSE REACTIONS

Hematologic Toxicity

Gastrointestinal Toxicity

Cardiac Toxicity

Pulmonary Toxicity

Secondary cancers.

Heart problems

Endocrine Toxicity

dermatologic changes. Delayed cardiac toxicity is typically observed several months or years after completion of treatment. This delayed cardiomyopathy is more extensive and severe than the early doserelated cardiomyopathy that occurs in patients given relatively high doses of anthracyclines. In patients with prior mediastinal/pericardial irradiation, concomitant use of other cardiotoxic agents, or left ventricular dysfunction at baseline, the risk of cardiac toxicity is increased. The risk of cardiac toxicity may be increased by other predisposing factors, including age and gender. In women, cardiac toxicity may be increased in patients with prior mediastinal/pericardial irradiation, concomitant use of other cardiotoxic agents, or left ventricular dysfunction at baseline. In patients with prior mediastinal/pericardial irradiation, concomitant use of other cardiotoxic agents, or left ventricular dysfunction at baseline, the risk of cardiac toxicity is increased. The risk of cardiac toxicity may be increased by other predisposing factors, including age and gender. In women, cardiac toxicity may be increased in patients with prior mediastinal/pericardial irradiation, concomitant use of other cardiotoxic agents, or left ventricular dysfunction at baseline.

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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 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 after 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 it continues or becomes more intense.

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

- fever
- chills
- decreased appetite
- muscle aches
- weakness
- weight loss
- more frequent or difficult urination
- pain when you urinate
- burning or pain with urination
- skin rash
- bleeding gums

- hair loss (alopecia). Your hair may re-grow after treatment.

- darkening of your nails or separation of your nails from your nailbed

- nausea
- vomiting
- lack of appetite or increased thirst
- bloated or more gas
- lower back or side pain
- abnormal heartbeat

- a secondary cancer may occur when Doxorubicin is combined with other chemotherapy agents or used for the treatment of blood disorders (myeloma) (membrane) may complete stop if you receive Doxorubicin.

Doxorubicin may or may not return after you complete your treatment of Doxorubicin.

The most common side effects of Doxorubicin are:

- hair loss (alopecia). Your hair may re-grow after treatment.
- darkening of your nails or separation of your nails from your nailbed
- nausea
- vomiting
- lack of appetite or increased thirst
- bloated or more gas
- lower back or side pain
- abnormal heartbeat

Infection. Call your doctor right away if you have any of the following symptoms of an allergic reaction:

- rash
- flushed face
- fever
- chills
- shortness of breath or trouble breathing

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

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

Tell your doctor and pharmacist about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements.

Your doctor and pharmacist will want to know if you are taking a medicine called calcium channel blockers, such as nifedipine, nicardipine, diltiazem, or verapamil. Treatment with these calcium channel blockers and Doxorubicin may increase the risk of life-threatening side effects (see "Other Side Effects of Doxorubicin"

When you start treatment with Doxorubicin, your doctor will give you instructions about when to take your medicine and how much medicine to take. Follow these instructions closely.

Doxorubicin is often given with other medicines. The effects of Doxorubicin may be different when it is used along with other medicines. Your doctor may change the dose of Doxorubicin or other medicines as needed.

Before you have any blood work test or surgery, tell your doctor or surgeon that you are taking Doxorubicin.

For more详细 information, please refer to the full prescribing information provided by the manufacturer.