Doxorubicin Hydrochloride for Injection, USP

Doxorubicin Hydrochloride is a cytotoxic anthracycline antibiotic isolated from cultures of Streptomyces peucetius var. caespitosus. It is an antibiotic that is lipophilic and can intercalate (insert) into DNA double helix.

Pharmacology
- **Mode of Action**
  - **Antitumor Activity**
    - **DNA Intercalation**
      - Doxorubicin binds to DNA by specific intercalation of its planar ring structure between base pairs. This interaction disrupts the DNA helix, leading to replication inhibition and cell death.
    - **DNA Topoisomerase II Inhibition**
      - Doxorubicin can also inhibit DNA topoisomerase II, leading to the formation of cleavable complexes and ultimately to cell death.

**Clinical Use**
- **Indications**
  - Cancer therapy: Doxorubicin is used in the treatment of various types of cancer, including breast cancer, lung cancer, and leukemia.

**Adverse Reactions**
- **Common**
  - Myelosuppression
  - Nausea and vomiting
  - Alopecia
- **Rare**
  - Cardiac toxicity

**Contraindications**
- Patients with known allergy to doxorubicin or any component of the formulation.

**Warnings and Precautions**
- Monitor cardiac function closely in patients treated with doxorubicin, especially those with pre-existing heart disease.

**Dosage and Administration**
- **Adults**
  - **Dose Adjustment**
    - Doxorubicin doses may need to be adjusted based on kidney and liver function.
    - **Monitoring**
      - Monitor patients for signs of cardiac toxicity, myelosuppression, and nephrotoxicity.

**Preparation and Administration**
- Doxorubicin should be administered through a central venous catheter and only in a hospital setting.

**Patient Information**
-**Side Effects**
  - **Common**
    - Nausea and vomiting
    - Alopecia
  - **Rare**
    - Cardiac toxicity

- **Storage and Handling**
- Doxorubicin is sensitive to light and should be stored at controlled room temperature and protected from light.\n
**Additional Information**
- Doxorubicin is a water-soluble anthracycline antibiotic and is available as a sterile solution for intravenous use.

**References**
- Clinical trials and published studies supporting the use of doxorubicin in various cancer indications.

This summary provides an overview of doxorubicin's pharmacology, clinical use, adverse reactions, contraindications, and dosing considerations. For detailed information, please consult the product's package insert and relevant medical literature.
Doxorubicin is a cardioprotectant, dexrazoxane, with the initiation of a regimen of fluorouracil, doxorubicin, cyclophosphamide (FAC) was associated with a lower tumor response rate. Later studies have shown that the addition of a cardiototoxic agent to FAC regimen results in a lower tumor response rate. However, the addition of dexrazoxane to the regimen has been shown to improve the tumor response rate, and the treatment has been associated with a lower incidence of serious cardiac events. The addition of dexrazoxane to the regimen has been shown to improve the tumor response rate, and the treatment has been associated with a lower incidence of serious cardiac events.

Drug Interactions

Cyclosporine

The administration of cyclosporine to doxorubicin may result in increased risk of nephrotoxicity. The concomitant use of cyclosporine with doxorubicin may result in a decrease in renal function. Therefore, it is recommended that the dose of cyclosporine be reduced in patients receiving doxorubicin. The concomitant use of doxorubicin with cyclosporine may result in a decrease in renal function. Therefore, it is recommended that the dose of cyclosporine be reduced in patients receiving doxorubicin.

Cytochrome P450

Doxorubicin is metabolized by the CYP2C19 and CYP3A4 enzymes. The concomitant use of drugs that inhibit these enzymes may result in an increase in doxorubicin exposure. Therefore, it is recommended that the dose of doxorubicin be reduced in patients receiving concomitant use of drugs that inhibit these enzymes.

Cyclophosphamide

Cyclophosphamide is a potent alkylating agent that can cause bone marrow suppression. The concomitant use of cyclophosphamide with doxorubicin may result in an increase in the risk of bone marrow suppression. Therefore, it is recommended that the dose of cyclophosphamide be reduced in patients receiving concomitant use of doxorubicin.

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Cyclophosphamide, Metabolism and Impairment of Fertility

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