

Ontologies Classes Object Properties Data Properties Annotation Properties Individuals Datatypes Clouds

## Class: Dosage\_and\_Administration\_DOXOR

### Annotations (1)

- rdfs:comment** "2.1 Recommended Dosage for Adjuvant Breast Cancer The recommended dosage of Doxorubicin Hydrochloride Injection/for Injection is 60 mg/m<sup>2</sup> administered as an intravenous bolus on day 1 of each 21-day treatment cycle, in combination with cyclophosphamide, for a total of four cycles. 2.2 Recommended Dosage for Other Cancers The recommended dosage of Doxorubicin Hydrochloride Injection/for Injection when used as a single agent is 60 mg/m<sup>2</sup> to 75 mg/m<sup>2</sup> intravenously every 21 days. The recommended dosage of Doxorubicin Hydrochloride Injection/for Injection, when administered in combination with other chemotherapy drugs, is 40 mg/m<sup>2</sup> to 75 mg/m<sup>2</sup> intravenously every 21 to 28 days. Consider use of the lower Doxorubicin Hydrochloride Injection/for Injection dose in the recommended dosage range or longer intervals between cycles for heavily pretreated patients, elderly patients, or obese patients. Cumulative doses above 550 mg/m<sup>2</sup> are associated with an increased risk of cardiomyopathy [see Warnings and Precautions (5.1)]. 2.3 Dosage Modifications for Adverse Reactions Cardiomyopathy Discontinue Doxorubicin Hydrochloride Injection/for Injection in patients who develop signs or symptoms of cardiomyopathy [see Warnings and Precautions (5.1)]. 2.4 Dosage Modifications for Hepatic Impairment Doxorubicin Hydrochloride Injection/for Injection is contraindicated in patients with severe hepatic impairment (Child-Pugh Class C or serum bilirubin greater than 5 mg/dL) [see Contraindications (4)]. Dosage modifications for Doxorubicin Hydrochloride Injection/for Injection in patients with elevated serum total bilirubin concentrations [see Warnings and Precautions (5.5), Use in Specific Populations (8.6)] are provided in Table 1. Table 1. Recommended Dosage Modification for Elevated Serum Total Bilirubin Serum total bilirubin concentration Dosage Modification 1.2 – 3 mg/dL 50% 3.1 – 5 mg/dL 75% greater than 5 mg/dL Do not initiate Doxorubicin Hydrochloride Injection/for Injection; discontinue Doxorubicin Hydrochloride Injection/for Injection 2.5 Preparation and Administration Doxorubicin Hydrochloride Injection/for Injection is a cytotoxic drug. Follow applicable special handling and disposal procedures.1 Preparation Reconstitution of Doxorubicin Hydrochloride for Injection Reconstitute Doxorubicin Hydrochloride for Injection with 0.9% Sodium Chloride Injection to obtain a final concentration of 2 mg per mL as follows: 5 mL 0.9% Sodium Chloride Injection, USP to reconstitute 10 mg vial 10 mL 0.9% Sodium Chloride Injection, USP to reconstitute 20 mg vial 25 mL 0.9% Sodium Chloride Injection, USP to reconstitute 50 mg vial 75 mL 0.9% Sodium Chloride Injection, USP to reconstitute 150 mg vial Gently shake vial until the contents have dissolved. Protect reconstituted solution from light. Dilution of Doxorubicin Hydrochloride Injection and Reconstituted Doxorubicin Hydrochloride for Injection Dilute Doxorubicin Hydrochloride Injection or reconstituted Doxorubicin Hydrochloride for Injection in 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Protect from light following preparation until completion of infusion. Use within 1 hour. If not used within 1 hour, discard the diluted product. Administration Visually inspect for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if the solution is discolored, cloudy, or contains particulate matter. Administration by Intravenous Injection Administer diluted Doxorubicin Hydrochloride Injection or diluted reconstituted Doxorubicin Hydrochloride for Injection as an intravenous injection through a central intravenous line or a secure and free-flowing peripheral venous line containing 0.9% Sodium Chloride Injection, USP, 0.45% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP. Administer intravenously over 3 to 10 minutes. Decrease the rate of infusion if erythematous streaking along the vein proximal to the site of infusion or facial flushing occur. Administration by Continuous Intravenous Infusion Administer diluted Doxorubicin Hydrochloride Injection solution or diluted reconstituted Doxorubicin Hydrochloride for Injection solution only through a central intravenous line. Decrease the rate of infusion if erythematous streaking along the vein proximal to the site of infusion or facial flushing occur. Protect from light from preparation for infusion until completion of infusion. Management of Suspected Extravasation Immediately discontinue Doxorubicin Hydrochloride Injection/for Injection for burning or stinging sensation or other evidence indicating peri-venous infiltration or extravasation. Manage confirmed or suspected extravasation as follows: Do not remove the needle until attempts are made to aspirate extravasated fluid. Do not flush the line. Avoid applying pressure to the site. Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. If the extravasation is in an extremity, elevate the extremity. In adults, consider administration of dexrazoxane [see Warnings and Precautions (5.3)]. Management of Contact with Skin or Eyes Treat accidental contact with the skin or eyes immediately by copious lavage with water, or soap and water, or sodium bicarbonate solution. Do not abrade the skin by using a scrub brush. Seek medical attention. Incompatibility with Other Drugs Do not admix Doxorubicin Hydrochloride Injection/for Injection with other drugs. If Doxorubicin Hydrochloride Injection/for Injection is mixed with heparin or fluorouracil, a precipitate may form. Avoid contact with alkaline solutions which can lead to hydrolysis of doxorubicin hydrochloride."(xsd:string)

### Superclasses (1)

- Doxorubicin\_Hydrochloride\_

**Disjoints (8)**

Adverse\_Reactions\_DOXOR, Contraindications\_DOXOR, **Dosage\_and\_Administration\_DOXOR**, Dosage\_Forms\_and\_Strengths\_DOXOR, Drug\_Interactions\_DOXOR, Indications\_and\_Usage\_DOXOR, Use\_in\_Specific\_Populations\_DOXOR, Warnings\_and\_Precautions\_DOXOR

OWL HTML inside