Ontologies Classes Object Properties Data Properties Annotation Properties Individuals Datatypes Clouds

Class: Use_in_Specific_Populations_DOXOR

Annotations (1)

- rdfs:comment ".1 Pregnancy Risk Summary Based on findings in animals and its mechanism of action, Doxorubicin Hydrochloride Injection/for Injection can cause fetal harm when administered to a pregnant woman; avoid the use of Doxorubicin Hydrochloride Injection/for Injection during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin hydrochloride during the 2nd and 3rd trimesters. Doxorubicin hydrochloride was teratogenic and embryotoxic in rats and embryotoxic in rabbits when administered during organogenesis at doses approximately 0.07 times (based on body surface area) the recommended human dose of 60 mg/m2 (see Data). Advise pregnant women of the potential risk to a fetus. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. Data Animal Data Doxorubicin hydrochloride was teratogenic and embryotoxic at doses of 0.8 mg/kg/day (about 0.07 times the recommended human dose based on body surface area) when administered during the period of organogenesis in rats. Teratogenicity and embryotoxicity were also seen using discrete periods of treatment. The most susceptible was the 6- to 9-day gestation period at doses of 1.25 mg/kg/day and greater. Characteristic malformations included esophageal and intestinal atresia, tracheo-esophageal fistula, hypoplasia of the urinary bladder, and cardiovascular anomalies. Doxorubicin hydrochloride was embryotoxic (increase in embryofetal deaths) and abortifacient at 0.4 mg/kg/day (about 0.07 times the recommended human dose based on body surface area) in rabbits when administered during the period of organogenesis. 8.2 Lactation Risk Summary Doxorubicin was measured in the milk of one lactating patient after therapy with 70 mg/m2 of doxorubicin hydrochloride given as a 15-minute intravenous infusion. The peak milk concentration at 24 hours after treatment was 4.4-fold greater than the corresponding plasma concentration. Doxorubicin was detectable in the milk up to 72 hours. There are no data on the effects of doxorubicin hydrochloride on the breastfed child or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Doxorubicin Hydrochloride Injection/for Injection and for 10 days after the final dose. 8.3 Females and Males of Reproductive Potential Pregnancy Testing Verify the pregnancy status of females of reproductive potential prior to initiating Doxorubicin Hydrochloride Injection/for Injection. Contraception Females Doxorubicin Hydrochloride Injection/for Injection can cause fetal harm when administered to pregnant women [see Use in Specific Populations (8.1)]. Advise female patients of reproductive potential to use highly effective contraception during treatment with Doxorubicin Hydrochloride Injection/for Injection and for 6 months after treatment. [see Use in Specific Populations (8.1)]. Males Doxorubicin hydrochloride may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Due to the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with Doxorubicin Hydrochloride Injection/for Injection and for 3 months after treatment [see Nonclinical Toxicology (13.1)]. Males with pregnant partners should use condoms during treatment and for at least 10 days after the final dose [see Nonclinical Toxicology (13.1), Use in Specific Populations (8.1)]. Infertility Females In females of reproductive potential, Doxorubicin hydrochloride may cause infertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment [see Nonclinical Toxicology (13.1)]. Males Doxorubicin hydrochloride 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 [see Nonclinical Toxicology (13.1)]. 8.4 Pediatric Use Based on postmarketing reports, pediatric patients treated with doxorubicin hydrochloride are at risk for developing late cardiovascular dysfunction. Risk factors include young age at treatment (especially < 5 years), high cumulative doses and receipt of combined modality therapy. Long-term periodic cardiovascular monitoring is recommended for all pediatric patients who have received doxorubicin hydrochloride. Doxorubicin hydrochloride, as a component of intensive chemotherapy regimens administered to pediatric patients, may contribute to prepubertal growth failure and may also contribute to gonadal impairment, which is usually temporary. There are no recommended dose adjustments based on age. Doxorubicin clearance was increased in patients aged 2 years to 20 years as compared to adults, while doxorubicin clearance was similar in infants less than 2 years as compared to adults [see Clinical Pharmacology (12.3)]. 8.5 Geriatric Use Clinical experience in patients who were 65 years of age and older who received doxorubicin hydrochloride-based chemotherapy regimens for metastatic breast cancer showed no overall differences in safety and effectiveness compared with younger patients. 8.6 Hepatic Impairment The clearance of doxorubicin was reduced in patients with elevated serum total bilirubin levels. Doxorubicin Hydrochloride Injection/for Injection is contraindicated in patients with severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin levels greater than 5 mg/dL) [see Contraindications (4)]. Reduce the dose of Doxorubicin Hydrochloride Injection/for Injection in patients

with serum total bilirubin levels greater than 1.2 mg/dL [See Dosage and Administration (2.4), Warnings and Precautions (5.5)]."(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

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