Ontologies Classes Object Properties Data Properties Annotation Properties Individuals Datatypes Clouds

Class: Adverse_Reactions_DOXOR

Annotations (1)

- rdfs:comment "The following clinically significant adverse reactions are described elsewhere in the labeling. Cardiomyopathy and Arrhythmias [see Warnings and Precautions (5.1)] Secondary Malignancies [see Warnings and Precautions (5.2)] Extravasation and Tissue Necrosis [see Warnings and Precautions (5.3)] Severe Myelosuppression [see Warnings and Precautions (5.4)] Tumor Lysis Syndrome [see Warnings and Precautions (5.6)] Radiation Sensitization and Radiation Recall [see Warnings and Precautions (5.7)] 6.1 Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Breast Cancer The safety data below were collected from 1492 women who received doxorubicin hydrochloride at a dose of 60 mg/m2 and cyclophosphamide at a dose of 600 mg/m2 (AC) every 3 weeks for 4 cycles for the adjuvant treatment of axillary lymph node positive breast cancer. The median number of cycles received was 4. Selected adverse reactions reported in this study are provided in Table 2. No treatment-related deaths were reported in patients on either arm of the study. Table 2. Selected Adverse Reactions in Patients with Early Breast Cancer Involving Axillary Lymph Nodes Adverse Reactions AC* N=1492 Conventional CMF N=739 % % AC = doxorubicin hydrochloride, cyclophosphamide; CMF = cyclophosphamide, methotrexate, fluorouracil * Includes pooled data from patients who received either AC for 4 cycles or AC for 4 cycles followed by CMF for 3 cycles Alopecia 92 71 Vomiting Vomiting ≤12 hours 34 25 Vomiting >12 hours 37 12 Intractable 5 2 Leukopenia Grade 3 (1,000–1,999 /mm3) 3.4 9.4 Grade 4 (<1000 /mm3) 0.3 0.3 Shock, sepsis 2 1 Systemic infection 2 1 Cardiac dysfunction Asymptomatic 0.2 0.1 Transient 0.1 0 Symptomatic 0.1 0 Thrombocytopenia Grade 3 (25,000–49,999 /mm3) 0 0.3 Grade 4 (<25,000 /mm3) 0.1 0 6.2 Postmarketing Experience The following adverse reactions have been identified during postapproval use of Doxorubicin Hydrochloride Injection/for Injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Cardiac – Cardiogenic shock Cutaneous – Skin and nail hyperpigmentation, oncolysis, rash, itching, photosensitivity, urticaria, acral erythema, palmar plantar erythrodysesthesia Gastrointestinal – Nausea, mucositis, stomatitis, necrotizing colitis, typhlitis, gastric erosions, gastrointestinal tract bleeding, hematochezia, esophagitis, anorexia, abdominal pain, dehydration, diarrhea, hyperpigmentation of the oral mucosa Hypersensitivity – Anaphylaxis Laboratory Abnormalities – Increased ALT, increased AST Neurological – Peripheral sensory and motor neuropathy, seizures, coma Ocular – Conjunctivitis, keratitis, lacrimation Vascular – Phlebosclerosis, phlebitis/thrombophlebitis, hot flashes, thromboembolism Other – Malaise/asthenia, fever, chills, weight gain"(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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