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Amiodarone HCl Injection (Nexterone)

??? ??????: 30 ??????/?????? 2017

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.

In a total of 1836 patients in controlled and uncontrolled clinical trials, 14% of patients received intravenous amiodarone for at least one week, 5% received it for at least 2 weeks, 2% received it for at least 3 weeks, and 1% received it for more than 3 weeks, without an increased incidence of severe adverse reactions. The mean duration of therapy in these studies was 5.6 days; median exposure was 3.7 days.

The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block. Overall, treatment was discontinued for about 9% of the patients because of adverse reactions. The most common adverse reactions leading to discontinuation of intravenous amiodaronejherapy were hypotension (1.6%), asystole/cardiac arrest/PEA (1.2%), VT (1.1%), and cardiogenic shock (1%).

Table 4 lists the most common (incidence ? 2%) adverse reactions during intravenous amiodarone therapy considered at least possibly drug-related. These data were collected in clinical trials involving 1836 patients with life-threatening VT/VF. Data from all assigned treatment groups are pooled because none of the adverse reactions appeared to be dose-related.

Table 4: ADVERSE REACTIONS IN PATIENTS RECEIVING INTRAVENOUS AMIODARONE IN CONTROLLED AND OPEN-LABEL STUDIES (? 2% INCIDENCE)

Study Event	Controlled Studies (n = 814)		Open-Label Studies (n = 1022)		Total (n = 1836)	
Body as a whole						
Fever	24	(2.9 %)	13	(1.2 %)	37	(2.0 %)
Cardiovascular System						
Bradycardia	49	(6.0 %)	41	(4.0 %)	90	(4.9 %)
Congestive heart failure	18	(2.2 %)	21	(2.0 %)	39	(2.1 %)
Heart arrest	29	(3.5 %)	26	(2.5 %)	55	(2.9 %)
Hypotension	165	(20.2 %)	123	(12.0 %)	288	(15.6 %)
Ventricular tachycardia	15	(1.8 %)	30	(2.9 %)	45	(2.4 %)
Digestive System						
Liver function tests abnormal	35	(4.2 %)	29	(2.8 %)	64	(3.4 %)
Nausea	29	(3.5 %)	43	(4.2 %)	72	(3.9 %)

Other adverse reactions reported in less than 2% of patients receiving intravenous amiodaronejn controlled and uncontrolled studies included the following: abnormal kidney function, atrial fibrillation, diarrhea, increased ALT, increased AST, lung edema, nodal arrhythmia, prolonged QT interval, respiratory disorder, shock, sinus bradycardia, Stevens-Johnson syndrome, thrombocytopenia, VF, and vomiting.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of amiodarone. 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.

anaphylactic/anaphylactoid reaction (including shock), fever ***Body as a Whole:***

hypotension (sometimes fatal), sinus arrest ***Cardiovascular:***

toxic epidermal necrolysis (sometimes fatal), exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, skin cancer, pruritus, ***Dermatologic:*** angioedema

syndrome of inappropriate antidiuretic hormone secretion (SIADH) ***Endocrine:***

pancytopenia, neutropenia, hemolytic anemia, aplastic anemia, thrombocytopenia, agranulocytosis, granuloma ***Hematologic:***

hepatitis, cholestatic hepatitis, cirrhosis ***Hepatic:***

pain, erythema, edema, pigment changes, venous thombosis, phlebitis, thrombophlebitis, cellulitis, necrosis, and skin sloughing ***Injection Site Reactions:***

myopathy, muscle weakness, rhabdomyolysis ***Musculoskeletal:***

hallucination, confusional state, disorientation, and delirium, pseudotumor cerebri ***Nervous System:***

pancreatitis ***Pancreatic:***

renal impairment, renal insufficiency, acute renal failure, ***Renal:***

bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest and ARDS), bronchiolitis obliterans organizing pneumonia ***Respiratory:*** (possibly fatal), dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates, and /or mass, pleuritis

thyroid nodules/thyroid cancer ***Thyroid:***

vasculitis ***Vascular:***