Skip to main content

BiDil (Isosorbide Dinitrate and Hydralazine Hcl)

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

BiDil (isosorbide dinitrate and hydralazine hcl)

BiDil (isosorbide dinitrate and hydralazine hcl) has been evaluated for safety in 517 heart failure patients in A-HeFT. A total of 317 of these patients received BiDil (isosorbide dinitrate and hydralazine hcl) for at least 6 months,and 220 received BiDil (isosorbide dinitrate and hydralazine hcl) for at least 12 months. In A-HeFT, 21% of the patients discontinued BiDil (isosorbide dinitrate and hydralazine hcl) for adverse experiences compared to 12% who discontinued placebo.Overall, adverse events were more common in BiDil (isosorbide dinitrate and hydralazine hcl) -treated than in placebo-treated patients. Table 2 lists adverse events reported with an incidence of ? 2% in patients treated with BiDil (isosorbide dinitrate and hydralazine hcl) in A-HeFT,and,after rounding to the nearest 1%, occurring more frequently than in the placebo group,regardless of causality. Headache and dizziness were the two most frequent adverse events and were more than twice as frequent in the BiDil (isosorbide dinitrate and hydralazine hcl) group. The most common reasons for discontinuing BiDil (isosorbide dinitrate and hydralazine hcl) in the A-HeFT trial were headache (7%) and dizziness (4%).

Table 2. Adverse Events Occurring in the A-HeFT Study in ? 2% of Patients Treated with BiDil (isosorbide dinitrate and hydralazine hcl) .

Placebo (N=527) (% of patients)	BiDil (isosorbide dinitrate and hydralazine hcl) (N=517) (% of patients)	
21	50	Headache
14	32	Dizziness
15	16	Chest pain
11	14	Asthenia
6	10	Nausea
7	8	Bronchitis
4	8	Hypotension
2	4	Sinusitis
2	4	Ventricular tachycardia
3	4	Palpitations
3	4	Hyperglycemia
3	4	Rhinitis
2	4	Paresthesia
2	4	Vomiting
1	3	Amblyopia
2	3	Hyperlipidemia
1	2	Tachycardia

The following adverse events were reported in A-HeFT in at least 1% but less than 2% of patients treated with BiDil (isosorbide dinitrate and hydralazine hcl) , and also occurred in at least 0.5% more patients than in placebo-treated patients; all such events are included unless they are too non-specific to be meaningful or appear to reflect underlying disease.

Allergic reaction,malaise.**Body as a Whole:**

Somnolence.**Central nervous system:**

Cholecystitis. **Gastrointestinal:**

Hypercholesteremia.**Metabolic:**

Arthralgia,myalgia, tendon disorder.**Musculoskeletal:**

Alopecia,angioedema,sweating.**Skin:**

In the V-HeFT I and II studies,a total of 587 patients with heart failure were treat-ed with the combination of isosorbide dinitrate and hydralazine hydrochloride. The type,pattern,frequency and severity of adverse experiences reported in these studies were similar to those reported in A-HeFT,and no unusual adverse experiences were reported.

Prior experience with BiDil (isosorbide dinitrate and hydralazine hcl) components

The following additional adverse events have been reported with hydralazine hydrochloride or isosorbide dinitrate but not necessarily with BiDil (isosorbide dinitrate and hydralazine hcl) :

paralytic ileus.**Digestive:**

paradoxical pressor response, crescendo angina.**Cardiovascular:**

peripheral neuritis, numbness,tingling, muscle cramps, psychotic reactions,disorientation.**Neurologic:**

difficulty in urination.**Genitourinary:**

blood dyscrasias,agranulocytosis,purpura,splenomegaly.**Hematologic:**

eosinophilia,hepatitis.**Hypersensitive Reactions:**

nasal congestion,flushing,lacrimation,conjunctivitis.**Other:**