Skip to main content

Dalvance (Dalbavancin for Injection)

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

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of DALVANCE cannot be directly compared to rates in the clinical trials of another drug and may not reflect rates observed in practice.

Adverse Reactions In Clinical Trials

Adverse reactions were evaluated for 1778 patients treated with DALVANCE and 1224 patients treated with comparator antibacterial drugs in seven Phase 2 and Phase 3 clinical trials. A causal relationship between study drug and adverse reactions was not always established. The median age of patients treated with DALVANCE was 47 years, ranging between 16 and 93 years old. Patients treated with DALVANCE were predominantly male (60%) and Caucasian (78%).

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation

Serious adverse reactions occurred in 109/1778 (6.1%) of patients treated with DALVANCE and in 80/1224 (6.5%) of patients treated with comparator. DALVANCE was discontinued due to an adverse reaction in 53/1778 (3%) patients and the comparator was discontinued due to an adverse reaction in 35/1224 (2.8%) patients.

Most Common Adverse Reactions

The most common adverse reactions in patients treated with DALVANCE were nausea (5.5%), headache (4.7%), and diarrhea (4.4%). The median duration of adverse reactions was 4.0 days in both treatment groups.

Table 1 lists selected adverse reactions occurring in more than 2% of patients treated with DALVANCE in clinical trials.

Table 1: Selected Adverse Reactions in Phase 2/3 Trials (Number (%) of Patients)

Comparator* (N = 1224)	Dalbavancin (N = 1778)	
78 (6.4)	98 (5.5)	Nausea
37 (3)	50 (2.8)	Vomiting
72 (5.9)	79 (4.4)	Diarrhea
59 (4.8)	83 (4.7)	Headache
30 (2.4)	48 (2.7)	Rash
41 (3.3)	38 (2.1)	Pruritus
* Comparators included linezolid, cefazolin, cephalexin, and vancomycin.		

The following selected adverse reactions were reported in DALVANCE treated patients at a rate of less than 2% in these clinical trials:

anemia, hemorrhagic anemia, leucopenia, neutropenia, thrombocytopenia, petechiae, eosinophilia, thrombocytosis **Blood and lymphatic system disorders:**

-gastrointestinal hemorrhage, melena, hematochezia, abdominal pain General Disorders and administration site conditions: infusion-**Gastrointestinal Disorders:** elated reactions

hepatotoxicity **Hepatobiliary disorders:**

anaphylactoid reaction **Immune system disorders:**

colitis, oral candidiasis, vulvovaginal mycotic infection *Clostridium difficile* **Infections and infestations:**

: hepatic transaminases increased, blood alkaline phosphatase increased, international normalized ratio increased.**Investigations**

hypoglycemia **Metabolism and nutrition disorders:**

dizziness **Nervous System disorders:**

bronchospasm **Respiratory, thoracic and mediastinal disorders:**

urticaria **Skin and Subcutaneous Tissue Disorders:**

flushing, phlebitis, wound hemorrhage, spontaneous hematoma **Vascular disorders:**

Alanine Aminotransferase (ALT) Elevations

Among patients with normal baseline ALT levels, more DALVANCE than comparator treated patients had post-baseline ALT elevations greater than 3 times the upper limit of normal (ULN), 12 (0.8%) vs. 2 (0.2%), respectively including three subjects with post-baseline ALT values greater than 10 times ULN. Eight of 12 patients treated with DALVANCE and one comparator patient had underlying conditions which could affect liver enzymes, including chronic viral hepatitis and a history of alcohol abuse. In addition, one DALVANCE-treated subject in a Phase 1 trial had post-baseline ALT elevations greater than 20 times ULN. ALT elevations were reversible in all subjects. No comparator-treated subject with normal baseline transaminases had post-baseline ALT elevation greater than 10 times ULN.