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Palonosetron HCl Capsules (Aloxi Capsules)

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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 clinical trials for the prevention of nausea and vomiting induced by moderately emetogenic chemotherapy, 693 adult patients received oral palonosetron in doses ranging from 0.25 mg to 0.75 mg. Following is a listing of drug related adverse reactions reported by ~2% of patients from two clinical trials.

Table 1: Adverse Reactions ~2% from Chemotherapy-Induced Nausea and Vomiting Studies

0.25 mg I.V. (N=163)	0.75 mg (N=375)	0.5 mg (N=161)	0.25 mg (N=157)	Event
14 (8.6%)	21 (5.6%)	6 (3.7%)	6 (3.8%)	Headache
5 (3.1%)	9 (2.4%)	1 (0.6%)	1 (0.6%)	Constipation

The infrequently reported adverse reactions listed below, assessed by investigators as treatment-related or causality unknown/missing, occurred following administration of ALOXI (palonosetron hcl capsules) Capsules to adult patients receiving concomitant cancer chemotherapy. Of these adverse events, fatigue (incidence 1%), was the only adverse event reported at an incidence of ~1%. In general, adverse reactions were similar between oral and I.V. formulations.

<1%: anemia. **Blood and Lymphatic System:**

<1%: hypertension, transient arrhythmia, first degree atrioventricular block, second degree atrioventricular block, QTc prolongation. **Cardiovascular:**

<1%: motion sickness. **Hearing and Labyrinth:**

<1%: eye swelling. **Eye:**

<1%: gastritis, nausea, vomiting. **Gastrointestinal System:**

1%: fatigue, <1%: chills, pyrexia. **General:**

<1%: sinusitis. **Infections:**

<1%: transient, asymptomatic increases in bilirubin. **Liver:**

<1%: anorexia. **Nutrition:**

<1%: joint stiffness, myalgia, pain in extremity. **Musculoskeletal:**

<1%: postural dizziness, dysgeusia. **Nervous System:**

<1%: insomnia. **Psychiatric:**

<1%: dyspnea, epistaxis. **Respiratory System:**

<1%: generalized pruritus, erythema, alopecia. **Skin:**

Very rare cases (<1/10,000) of hypersensitivity reactions have been reported for I.V. ALOXI (palonosetron hcl capsules) from post-marketing experience.

