HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ALOXI Capsules safely and effectively. See full prescribing information for ALOXI.

ALOXI (palonosetron HCl) Capsules
Initial U.S. Approval: 2003

----------INDICATIONS AND USAGE----------
ALOXI Capsules, a serotonin subtype 3 (5-HT_3) receptor antagonist, are indicated for:

- Moderately emetogenic cancer chemotherapy -- prevention of acute nausea and vomiting associated with initial and repeat courses (1.1)

----------DOSAGE AND ADMINISTRATION----------
Adult Dosage: one 0.5 mg capsule administered approximately one hour prior to the start of chemotherapy (2.1)

ALOXI can be taken with or without food (12.3)

----------DOSAGE FORMS AND STRENGTHS----------
0.5 mg capsule (3)

----------CONTRAINDICATIONS----------
ALOXI is contraindicated in patients known to have hypersensitivity to the drug or any of its components (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT_3 receptor antagonists (5.1)

----------ADVERSE REACTIONS----------
No adverse reactions have been reported at an incidence of ≥5% for the 0.5 mg dose. Headache and constipation are the most common adverse reactions but occur less frequently (6)

To report SUSPECTED ADVERSE REACTIONS, contact EISAI at 1-888-422-4743) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------
The potential for clinically significant drug interactions with palonosetron appears to be low (7)

----------USE IN SPECIFIC POPULATIONS----------
Safety and effectiveness in patients below the age of 18 years have not been established (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: [08/2008]

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Prevention of Chemotherapy-Induced Nausea and Vomiting

ALOXI Capsules are indicated for:

- Moderately emetogenic cancer chemotherapy - prevention of acute nausea and vomiting associated with initial and repeat courses

2. DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Dosage for Adults - one 0.5 mg capsule administered approximately one hour prior to the start of chemotherapy. ALOXI can be taken with or without food.

3 DOSAGE FORMS AND STRENGTHS

Capsules, 0.5 mg

4 CONTRAINDICATIONS

ALOXI is contraindicated in patients known to have hypersensitivity to the drug or any of its components.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT_3 receptor antagonists**.** Hypersensitivity reactions have been very rarely reported postmarketing for intravenous palonosetron: dyspnea, bronchospasm, swelling/edema, erythema, pruritus, rash, urticaria. No hypersensitivity reactions have been reported for oral palonosetron.

6 ADVERSE REACTIONS

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.

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

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

The infrequently reported adverse reactions listed below, assessed by investigators as treatment-related or causality unknown/missing, occurred following administration of ALOXI 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.

Blood and Lymphatic System: <1%: anemia.

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

Hearing and Labyrinth: <1%: motion sickness.

Eye: <1%: eye swelling.

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

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

Infections: <1%: sinusitis.

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

Nutrition: <1%: anorexia.

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

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

Psychiatric: <1%: insomnia.

Respiratory System: <1%: dyspnea, epistaxis.

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

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

7 DRUG INTERACTIONS

Palonosetron is eliminated from the body through both renal excretion and metabolic pathways with the latter mediated via multiple CYP enzymes. Further *in vitro* studies indicated that palonosetron is not an inhibitor of CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2D6, CYP2E1 and CYP3A4/5 (CYP2C19 was not investigated) nor does it induce the activity of CYP1A2, CYP2D6, or CYP3A4/5. Therefore, the potential for clinically significant drug interactions with palonosetron appears to be low.

A study in healthy volunteers involving single-dose I.V. palonosetron (0.75 mg) and steady state oral metoclopramide (10 mg four times daily) demonstrated no significant pharmacokinetic interaction.

Concomitant administration of an antacid (Maalox® liquid 30 mL) had no effect on the oral absorption or pharmacokinetics of a single capsule of palonosetron 0.75 mg in healthy subjects.

In controlled clinical trials, ALOXI Capsules have been safely administered with chemotherapeutic agents, systemic corticosteroids, analgesics, and drugs for gastrointestinal disorders including function gastrointestinal disorders, acid-related disorders, and antiemetics/antinauseants.

Palonosetron did not inhibit the antitumor activity of the five chemotherapeutic agents tested (cisplatin, cyclophosphamide, cytarabine, doxorubicin and mitomycin C) in murine tumor models.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic effects

Pregnancy Category B. Reproduction studies have been performed in rats at oral doses up to 60 mg/kg/day (921 times the recommended human oral dose based on body surface area) and rabbits at oral doses up to 60 mg/kg/day (1841 times the recommended human oral dose based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to palonosetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, palonosetron should be used during pregnancy only if clearly needed.

8.2 Labor and Delivery

Palonosetron has not been administered to patients undergoing labor and delivery, so its effects on the mother or child are unknown.

8.3 Nursing Mothers

It is not known whether palonosetron is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants and the potential for tumorigenicity shown for palonosetron in the rat carcinogenicity study, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness in patients below the age of 18 years have not been established.

8.5 Geriatric Use

Of the total number of adult cancer patients in a pivotal study of oral palonosetron, 181 were 65 years of age and over. The number of geriatric

patients receiving 0.5 mg palonosetron was insufficient to draw any efficacy or safety conclusions.

In a cross-study comparison, after a single oral dose (0.75 mg) the systemic exposure of palonosetron (AUC) was similar, but mean C_{max} was 15% lower in healthy elderly subjects ≥65 years of age compared with the subjects < 65 years of age. No dose adjustment is required for geriatric patients.

8.6 Renal Impairment

Mild to moderate renal impairment does not significantly affect palonosetron pharmacokinetic parameters. Total systemic exposure to intravenous ALOXI increased by approximately 28% in severe renal impairment relative to healthy subjects. Dosage adjustment is not necessary in patients with mild to severe renal impairment. The pharmacokinetics of palonosetron have not been studied in subjects with end-stage renal disease.

8.7 Hepatic Impairment

Hepatic impairment does not significantly affect total body clearance of intravenous palonosetron compared to the healthy subjects. Dosage adjustment is not necessary in patients with any degree of hepatic impairment.

8.8 Race

Oral pharmacokinetics of palonosetron were characterized in thirty-two healthy Japanese male subjects using solution over the dose range of 3-90 µg/kg. The apparent total body clearance was 26% higher in Japanese males than in white males based on a cross-study comparison; however, no dose adjustment is necessary. The pharmacokinetics of palonosetron in other races have not been adequately characterized.

8.9 Gender

Although a single dose of 0.5 mg ALOXI Capsule was associated with a 26-35% higher systemic exposure in female subjects than in male subjects, dosage adjustment is not necessary based on gender.

10 OVERDOSAGE

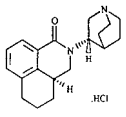
There is no known antidote to ALOXI. Overdose should be managed with supportive care.

Thirty-three adult cancer patients were administered oral palonosetron at a dose of 90 µg/kg (equivalent to 6 mg fixed dose) as part of a dose ranging study. This is approximately 12 times the recommended oral dose of 0.5 mg. This dose group had a similar incidence of adverse events compared to the other dose groups and no dose response effects were observed.

Dialysis studies have not been performed, however, due to the large volume of distribution, dialysis is unlikely to be an effective treatment for palonosetron overdose. A single oral dose of palonosetron at 500 mg/kg in rats and 100 mg/kg in dogs (7673 and 5115 times the recommended human oral dose, respectively, based on body surface area) was lethal. The major signs of toxicity included convulsions, labored breathing, and salivation.

11 DESCRIPTION

ALOXI (palonosetron HCl) Capsules is an antiemetic and antinauseant agent. It is a serotonin subtype 3 (5-HT_3) receptor antagonist with a strong binding affinity for this receptor. Chemically, palonosetron hydrochloride is: (3a<u>S</u>)-2-[(<u>S</u>)-1-Azabicyclo [2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1*H*-benz[*de*]isoquinoline hydrochloride. The empirical formula is $C_{19}H_{24}N_2O.HCl$, with a molecular weight of 332.87. Palonosetron hydrochloride exists as a single isomer and has the following structural formula:



Palonosetron hydrochloride is a white to off-white crystalline powder. It is freely soluble in water, soluble in propylene glycol, and slightly soluble in ethanol and 2-propanol.

Each light beige opaque soft gelatin ALOXI Capsule contains 0.56 mg of palonosetron HCl equivalent to palonosetron 0.5 mg. Inactive ingredients are: mono- and di-glycerides of capryl/capric acid, glycerin, polyglyceryl oleate, water, and butylated hydroxyanisole.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Palonosetron is a 5-HT_3 receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors.

Cancer chemotherapy may be associated with a high incidence of nausea and vomiting, particularly when certain agents, such as cisplatin, are used. 5-HT_3 receptors are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger zone of the area postrema. It is thought that chemotherapeutic agents produce nausea and vomiting by releasing serotonin from the enterochromaffin cells of the small intestine and that the released serotonin then activates 5-HT_3 receptors located on vagal afferents to initiate the vomiting reflex.

12.2 Pharmacodynamics

In non-clinical studies palonosetron possesses the ability to block ion channels involved in ventricular de- and re-polarization and to prolong action potential duration.

The effect of palonosetron on QTc interval was evaluated in a double blind, randomized, parallel, placebo and positive (moxifloxicin) controlled trial in adult men and women. The objective was to evaluate the ECG effects of intravenously administered palonosetron at single doses of 0.25 mg, 0.75 mg or 2.25 mg in 221 healthy subjects. The study demonstrated no significant effect on any ECG interval including QTc duration (cardiac repolarization) at doses up to 2.25 mg.

Clinical trials revealed that oral palonosetron had comparable effects on blood pressure, heart rate, and ECG parameters as intravenous palonosetron.

12.3 Pharmacokinetics

<u>Absorption</u>

Following oral administration, palonosetron is well absorbed with its absolute bioavailability reaching 97%. After single oral doses using buffered solution mean maximum palonosetron concentrations (C_{max}) and area under the concentration-time curve ($AUC_{0-\infty}$) were dose proportional over the dose range of 3.0 to 80 µg/kg in healthy subjects.

In 36 healthy male and female subjects given a single oral dose of ALOXI Capsules 0.5 mg, maximum plasma palonosetron concentration (C_{max}) was 0.81 ± 1.66 ng/mL (mean ± SD) and time to maximum concentration (T_{max}) was 5.1 ± 1.7 hours. In female subjects (n=18), the mean AUC was 35% higher and the mean C_{max} was 26% higher than in male subjects (n=18).

In 12 cancer patients given a single oral dose of palonosetron 0.5 mg one hour prior to chemotherapy, C_{max} was 0.93 ± 0.34 ng/mL and T_{max} was 5.1 ± 5.9 hours. The AUC was 30% higher in cancer patients than in healthy subjects. The mean PK parameters after a single oral dose of 0.5 mg palonosetron are compared between healthy subjects and cancer patients (Table 2).

Table 2: Mean PK parameters[1] (± SD) of palonosetron after a single dose of 0.5 mg Aloxi Capsules in healthy subjects and cancer patients

PK Parameters	Healthy subjects (n=36)	Cancer patients (n=12)
C_{max} (ng/mL)	0.81 ± 0.17	0.93 ± 0.34
T_{max} (h)	5.1 ± 1.7	5.1 ± 5.9
AUC_{∞} (ng·h/mL)	38.2 ± 11.7	49.7 ±12.2
$t_{1/2}$ (h)	37 ± 12	48 ± 19

[1] a cross-study comparison

A high fat meal did not affect the Cmax and AUC of oral palonosetron. Therefore, ALOXI Capsules may be taken without regard to meals.

<u>Distribution</u>

Palonosetron has a volume of distribution of approximately 8.3 ± 2.5 L/kg. Approximately 62% of palonosetron is bound to plasma proteins.

<u>Metabolism</u>

Palonosetron is eliminated by multiple routes with approximately 50% metabolized to form two primary metabolites: N-oxide-palonosetron and 6-S-hydroxy-palonosetron. These metabolites each have less than 1% of the 5-HT_3 receptor antagonist activity of palonosetron. *In vitro* metabolism studies have suggested that CYP2D6 and to a lesser extent, CYP3A4 and CYP1A2 are involved in the metabolism of palonosetron. However, clinical

pharmacokinetic parameters are not significantly different between poor and extensive metabolizers of CYP2D6 substrates.

Elimination

Following administration of a single oral 0.75 mg dose of [^{14}C]-palonosetron to six healthy subjects, 85% to 93% of the total radioactivity was excreted in urine, and 5% to 8% was eliminated in feces. The amount of unchanged palonosetron excreted in the urine represented approximately 40% of the administered dose. In healthy subjects given ALOXI Capsules 0.5 mg, the terminal elimination half-life (t½) of palonosetron was 37 ± 12 hours (mean ± SD), and in cancer patients, t½ was 48 ± 19 hours. After a single-dose of approximately 0.75 mg intravenous palonosetron, the total body clearance of palonosetron in healthy subjects was 160 ± 35 mL/h/kg (mean ± SD) and renal clearance was 66.5 ± 18.2 mL/h/kg.

Special Populations

[see USE IN SPECIFIC POPULATIONS (8.5-8.9)]

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, animals were treated with oral doses of palonosetron at 10, 30 and 60 mg/kg/day. Treatment with palonosetron was not tumorigenic. The highest tested dose produced a systemic exposure to palonosetron (Plasma AUC) of about 90 to 173 times the human exposure (AUC= 49.7 ng·h/mL) at the recommended oral dose of 0.5 mg. In a 104-week carcinogenicity study in Sprague-Dawley rats, male and female rats were treated with oral doses of 15, 30 and 60 mg/kg/day and 15, 45 and 90 mg/kg/day, respectively. The highest doses produced a systemic exposure to palonosetron (Plasma AUC) of 82 and 185 times the human exposure at the recommended dose. Treatment with palonosetron produced increased incidences of adrenal benign pheochromocytoma and combined benign and malignant pheochromocytoma, increased incidences of pancreatic Islet cell adenoma and combined adenoma and carcinoma and pituitary adenoma in male rats. In female rats, it produced hepatocellular adenoma and carcinoma and increased the incidences of thyroid C-cell adenoma and combined adenoma and carcinoma.

Palonosetron was not genotoxic in the Ames test, the Chinese hamster ovarian cell (CHO/HGPRT) forward mutation test, the *ex vivo* hepatocyte unscheduled DNA synthesis (UDS) test or the mouse micronucleus test. It was, however, positive for clastogenic effects in the Chinese hamster ovarian (CHO) cell chromosomal aberration test.

Palonosetron at oral doses up to 60 mg/kg/day (about 921 times the recommended human oral dose based on body surface area) was found to have no effect on fertility and reproductive performance of male and female rats.

14 CLINICAL STUDIES

Study 1 was a multicenter, randomized, double-blind active control clinical trial of 635 patients set to receive moderately emetogenic cancer chemotherapy. A single-dose of 0.25 mg, 0.5 mg, or 0.75 mg oral ALOXI capsules given one hour prior to moderately emetogenic chemotherapy was compared to a single-dose of 0.25 mg I.V. ALOXI given 30 minutes prior to chemotherapy. Patients were randomized to either dexamethasone or placebo in addition to their assigned treatment. The majority of patients in the study were women (73%), white (69%), and naïve to previous chemotherapy (59%). The primary efficacy endpoint was Complete Response (no emetic episodes and no rescue medication) assessed in the acute phase (0-24 hours). A key secondary efficacy endpoint was Complete Response assessed in the delayed phase (24-120 hours). Other secondary endpoints included Complete Response for the acute plus delayed phases (0-120 hours) and No Nausea for the acute and delayed phases.

Efficacy was based on demonstrating non-inferiority of oral palonosetron doses compared to the approved I.V. formulation. Non-inferiority criteria were met if the lower bound of the two-sided 98.3% confidence interval for the difference in complete response rates of oral palonosetron dose minus approved I.V. formulation was larger than -15%. The non-inferiority margin was 15%.

Efficacy Results

As shown in Table 3, ALOXI Capsules 0.5 mg demonstrated non-inferiority to the active comparator during the 0 to 24 hour time interval; however, for the 24 to 120 hour time period, non-inferiority was not shown. The additional two oral palonosetron dose levels showed similar results.

Table 3: Proportion of Patients Achieving Complete Response Post-Chemotherapy

Time Period	Oral ALOXI 0.5 mg (N=160)	I.V. ALOXI 0.25 mg (N=162)	Difference [Two-sided 98.3% Confidence Interval]*: Oral ALOXI minus I.V. ALOXI Comparator
0-24 hr	76.3%	70.4%	5.9% [-6.5%, 18.2%]
24-120 hr	62.5%	65.4%	-2.9% [-16.3%, 10.5%]

* To adjust for multiplicity of treatment groups, a lower-bound of a two-sided 98.3% confidence interval was used to compare to -15%, the negative value of the non-inferiority margin.

As indicated in the data above, analysis of the key secondary endpoint showed that a single dose of ALOXI Capsules 0.5 mg was numerically similar to a single dose of I.V. ALOXI 0.25 mg, however, statistical non-inferiority was not demonstrated. For ALOXI Capsules 0.5 mg versus I.V. ALOXI 0.25 mg, the proportion of patients with complete response at 0-120 hours was 58.8% versus 59.3%, respectively. The proportions of patients with no nausea at 0-24 and 24-120 hours were also numerically similar between oral and I.V. doses.

Study 2 was a multicenter, open label, repeat cycle study performed to evaluate the safety and efficacy of single dose oral ALOXI Capsules 0.75 mg in cancer patients receiving moderately emetogenic chemotherapy. An ALOXI capsule was given to 217 cancer patients in 654 chemotherapy cycles one hour before the start of chemotherapy. Approximately 74% of patients also received single dose oral or intravenous dexamethasone 30 minutes before chemotherapy. Complete Response was not formally evaluated for the repeat cycle application. However, in general the antiemetic effect for the 0-24 hour interval was similar throughout the consecutively repeated cycles.

16 HOW SUPPLIED/STORAGE AND HANDLING

NDC #62856-799-05, ALOXI Capsules, 0.5 mg (free base), are supplied as light beige opaque soft gelatin capsules, five capsules per bottle, each bottle packaged in a small carton.

Storage

- Store at 25ºC (77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].
- Protect from light.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.2)

17.1 Instructions for Patients

- Patients should be instructed to read the patient insert.

17.2 FDA-Approved Patient Labeling

Patient Information

ALOXI® (Ah-lock-see)

(palonosetron HCl)
Capsules

Read the Patient Information that comes with ALOXI before you start taking it and each time you refill your prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ALOXI?

ALOXI is a prescription medicine used in adults to help prevent the nausea and vomiting that happens with certain anti-cancer medicines (chemotherapy).

It is not known if ALOXI is safe and effective in people under the age of 18 years.

Who should not take ALOXI?

Do not take ALOXI if you are allergic to any of the ingredients in ALOXI. See the end of this leaflet for a complete list of ingredients in ALOXI.

What should I tell my doctor before taking ALOXI?

Tell your doctor about all of your medical conditions, including if you:

- have had an allergic reaction to another medicine for nausea or vomiting, such as Kytril (granisetron), Anzemet (dolasetron), Zofran (ondansetron), or to the medicine Lotronex (alosetron).
- **are pregnant**. It is not known if ALOXI may harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- **are breast-feeding or plan to breast-feed**. It is not known if ALOXI passes into your milk. You and your doctor should decide if you will take ALOXI or breast-feed. You should not do both.

How should I take ALOXI?

- Take ALOXI exactly as prescribed by your doctor.
- Take one ALOXI Capsule by mouth about one hour before you get your anti-cancer medicine (chemotherapy).
- ALOXI can be taken with or without food.
- If you take too much ALOXI, tell your doctor right away.

What are the possible side effects of ALOXI?

Serious allergic reactions. Serious allergic reactions can happen with ALOXI. Tell your doctor if you experience redness or swelling of the skin, itching, chest discomfort or shortness of breath.

The most common side effects of ALOXI are:

- headache
- constipation
- tiredness (fatigue)

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ALOXI. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ALOXI?

- Store ALOXI at 59^{0}F to 86^{0}F (15^{0}C to 30^{0}C).
- Keep ALOXI away from light

Keep ALOXI out of the reach of children.

General information about ALOXI

Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. Do not take ALOXI for a condition for which it was not prescribed. Do not give ALOXI to other people even if they have the same condition that you have. It may harm them.

This leaflet summarizes the most important information about ALOXI. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ALOXI that is written for health professionals. For more information call 1-888-422-4743, or go to www.ALOXI.com.

What are the ingredients in ALOXI?

Active ingredient: palonosetron hydrochloride
Inactive ingredients: Mono-glycerides and di-glycerides of capryl/capric acid, glycerin, polyglyceryl oleate, water, and butylated hydroxyanisole

Jointly manufactured by Catalent Pharma Solutions, Somerset NJ and Philadelphia PA, USA, and Helsinn Birex Pharmaceuticals, Dublin, Ireland
HELSINN, Manufactured for Helsinn Healthcare SA, Switzerland

Distributed and marketed by Eisai Inc., Woodcliff Lake, NJ 07677

ALOXI® is a registered trademark of Helsinn Healthcare SA, Lugano, Switzerland

Revised 08/2008