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Featured Topic



Statins: Cholesterol Lowering Drugs

Statins are a class of drugs that reduce cholesterol. Learn the differences among the statins, how they work and potential side effects and drug interactions.

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Top 200 Drugs

BY NAMES SEARCHED BY PRESCRIPTIONS DISPENSED

A	Lovenox
Abilify	Lunesta
Accutane	Lyrica
Aciphex	M
Actos	Macrobid
Acyclovir	Meclizine
Adderall XR	Medrol
Adderall	Meridia
Advair	Methadone
Albuterol	Methotrexate
Aldactone	Mevacor
Allegra	Mirapex
Allopurinol	Mirena
Altace	Mobic
Ambien	Morphine
Amiodarone	Motrin
Amoxicillin	MS-Contin
Aricept	Mucomyst
Atarax	N
Atenolol	Naprosyn
Ativan	Neurontin

New Drugs at RxList

Aloxi (palonosetron HCl) Capsules	Navstel (balanced salt ophthalmic solution with hypromellose, dextrose and glutathione) Sterile
Augmentin (amoxicillin/clavulanate potassium) Chewable Tablets	Nplate (romiplostim)
Capastat Sulfate (capremycin) Injection	Propranolol Hydrochloride Injection
Cleviprex (clevidipine butyrate)	Rythmol SR (propafenone hydrochloride) Extended-Release Capsules
Erythrocin Stearate (erythromycin stearate) Tablets	Stavzor (valproic acid) Delayed-Release Capsules
Gammagard Liquid (immune globulin intravenous human %10)	Targretin (bexarotene) Gel
Haldol Decanoate 50 (haloperidol)	Theophylline in %5 Dextrose Injection
MetroCream (metronidazole) Topical Cream	Tigan (trimethobenzamide hydrochloride) Injectable
MetroGel 75 (metronidazole) Topical Gel	Vectibix (panitumumab) Injection
Myleran (busulfan) Tablets	

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Ringworm
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Accolate (zafirlukast) Tablets	Metrotion (metronidazole) Tropical Lotion
Aciphex (rabeprazole sodium) Delayed Release Tablets	Neosporin (neomycin and polymyxin B sulfates and bacitracin zinc) Ophthalmic Ointment
Aminonide	Nimotop (nimodipine) Capsules
Aminonide Lotion	Ontak (denileukin difitox)
Avastin (bevacizumab)	Oxacillin (oxacillin) Injection
Benefix Coagulation Factor IX	Pilopine HS (pilocarpine hydrochloride) Ophthalmic Gel
Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) Injectable Suspension	Podocon-25 (25% podophyllin in benzoin tincture)
Copegus (ribavirin) Tablets	Polymyxin B for Injection
Corzide (nadolol and bendroflumethiazide) Tablets	Precose (acarbose) Tablets
Cortrosyn (cosyntropin) Injection	Prozac (fluoxetine)
Delestrogen (estradiol valerate)Injection	Qvar (beclomethasone dipropionate)
Elmiron (pentosan polysulfate sodium) Capsules	Recombivax HB (recombinant)
Eloxatin (oxaliplatin)	Retavase (reteplase, recombinant)
Enablex (darifenacin) Extended-Release Capsules	Sodium Bicarbonate Injection
Erygel (erythromycin topical) Gel	Somavert (pegvisomant) Injection
Fludeoxyglucose F 18 (FDG) Injection	Sprycel (dasatinib) Tablet
Gammagard (immune globulin) Intravenous	Survanta (beractant) Intratracheal Suspension
Gantrisin (acetyl sulfisoxazole) Pediatric Suspension	Sustiva (efavirenz) Capsules and Tablets
Glyset (miglitol) Tablets	Synagis (palivizumab)
Grifulvin V (griseofulvin)	Talacen (pentazocine hydrochloride and acetaminophen)
Kloron (sodium sulfacetamide) Lotion	Targretin (bexarotene) Capsules
Lopressor HCT (metoprolol tartrate and hydrochlorothiazide) Tablet	Thyrogen (thyrotropin alfa) Injection
Loetrin 24 fe	Trimpex (trimethoprim) Tablet
Menomune (menigococcal polysaccharide) Vaccine	MetroGel 75 (metronidazole) Topical Gel
MetroGel (metronidazole) Gel	Vepesid (etoposide) Capsules
	Vidaza (azacitidine) Injection
	Vincristine Sulfate Injection
	Vytorin (ezetimibe/simvastatin) Tablets

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- Neurontin
- Prometrium
- Strattera

Drugs A-Z List - P

A-Z Drug List [Browse by brand or generic name]

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

P → [Pa-Pb](#) [Pc-Pe](#) [Pf-Ph](#) [Pi-Pm](#) [Pn-Pq](#) [Pr-Pr](#) [Ps-Pz](#)

Pa-Pb

- Paclitaxel (Taxol)
- Palifermin (Kepivance)
- Paliperidone (Invega)
- Palivizumab (Synagis)
- Palonosetron HCl Capsules (Aloxi Capsules)
- Palonosetron hydrochloride (Aloxi)
- Pamelor (Nortriptyline HCl)
- Pamidronate Disodium (Aredia)
- Pancrecarb (Pancrelipase)
- Pancrelipase (Pancrecarb)
- Pancrelipase (Ultrase)
- Pancrelipase (Viokase)
- Pancrelipase Delayed-Released Capsules (Creon 10)
- Pancrelipase Delayed-Released Capsules (Creon 20)
- Pandel (Hydrocortisone Probutate Cream)
- Panhematin (Hemin)
- Panitumumab Injection for Intravenous Use (Vectibix)
- Panretin (Alitretinoin)
- Pantoprazole (Protonix Tablets)
- Pantoprazole Sodium (Protonix I.V.)
- Papain and Urea (Accuzyme)
- Papaverine (Papaverine)
- Papaverine Hydrochloride Injection (Papaverine Injection)
- Papaverine Injection (Papaverine Hydrochloride Injection)
- Parafon Forte (Chlorzoxazone)
- Paraplatin (Carboplatin)
- Paregoric (Anhydrous Morphine)
- Paremyd (Hydroxyamphetamine Hydrobromide, Tropicamide)
- Paricalcitol (Zemplar Capsules)
- Paricalcitol Injection Fliptop Vial (Zemplar Injection)
- Parlodel (Bromocriptine Mesylate)
- Parnate (Tranlycypromine)
- Paromomycin Sulfate (Paromomycin Sulfate Capsules)
- Paromomycin Sulfate Capsules (Paromomycin Sulfate)
- Paroxetine Hydrochloride (Paxil)
- Paroxetine Hydrochloride (Paxil-CR)
- Paroxetine Mesylate (Asimia)
- Paroxetine Mesylate (Pexeva)

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Viagra
Zyrtec

[Paser \(Aminosalicylic Acid\)](#)

[Pataday \(Olopatadine Hydrochloride Ophthalmic Solution\)](#)

[Patanase Nasal Spray \(Olopatadine Hydrochloride Nasal Spray\)](#)

[Patanol \(Olopatadine\)](#)

[Paxil \(Paroxetine Hydrochloride\)](#)

[Paxil-CR \(Paroxetine Hydrochloride\)](#)

[↑ Back to Top](#)**Pc-Pe**

[PCE \(Erythromycin PCE\)](#)

[Pediapred \(Prednisolone Sodium\)](#)

[PediTRACE \(PedTRACE\)](#)

[Pediazole \(Erythromycin and Sulfisoxazole\)](#)

[Pediolic \(Neomycin, Polymyxin B and Hydrocortisone\)](#)

[PedTRACE \(PediTRACE\)](#)

[Pevax HIB \(Haemophilus b Conjugate Vaccine\)](#)

[PEG Electrolytes Solution \(Go-Lytely\)](#)

[PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride \(TriLyte\)](#)

[PEG-3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, Ascorbic Acid \(MoviPrep\)](#)

[Peg-Intron \(Peginterferon alfa-2b\)](#)

[Pegademase Bovine \(Adagen\)](#)

[Peganone \(Ethotoin\)](#)

[Pegaptanib Sodium \(Macugen\)](#)

[Pegaspargase \(Oncaspar\)](#)

[Pegasys \(Peginterferon alfa-2a\)](#)

[Pegfilgrastim \(Neulasta\)](#)

[Peginterferon alfa-2a \(Pegasys\)](#)

[Peginterferon alfa-2b \(Peg-Intron\)](#)

[Pegvisomant \(Somavert\)](#)

[Pemetrexed \(Alimta\)](#)

[Pemirolast potassium \(Alamast\)](#)

[Pemoline \(Cylert\)](#)

[Penciclovir \(Denavir\)](#)

[Penetrex \(Enoxacin\)](#)

[Penicillamine \(Cuprimine\)](#)

[Penicillin G Benzathine and Penicillin G Procaine Inj \(Bicillin C-R 900/300\)](#)

[Penicillin G Benzathine and Penicillin G Procaine Inj \(Bicillin C-R Tubex\)](#)

[Penicillin G Benzathine and Penicillin G Procaine Inj \(Bicillin CR\)](#)

[Penicillin G Benzathine Injectable in Tubex \(Bicillin L-A Injectable in Tubex\)](#)

[Penicillin G Potassium \(Penicillin G Potassium\)](#)

[Penicillin G potassium \(Pfizerpen\)](#)

[Penicillin V Potassium \(Penicillin VK\)](#)

[Penicillin VK \(Penicillin V Potassium\)](#)

[Penlac \(Ciclopirox Topical Solution\)](#)

[Pentacel \(Tetanus Toxoid Conjugate\)](#)

[Pentamidine Isethionate \(Nebupent\)](#)

[Pentasa \(Mesalamine\)](#)

[Pentazocine and Acetaminophen \(Talacen\)](#)

[Pentazocine and Aspirin \(Talwin Compound\)](#)

[Pentazocine and Naloxone \(Talwin Nx\)](#)

[Pentetate Calcium Trisodium Inj \(Ca-DTPA\)](#)

[Pentetate Zinc Trisodium Inj \(Zn-DTPA\)](#)
[Pentobarbital \(Nembutal\)](#)
[Pentosan \(Elmiron\)](#)
[Pentothal \(Thiopental Sodium\)](#)
[Pentoxifylline \(Trental\)](#)
[Pepcid \(Famotidine\)](#)
[Pepcid Injection \(Famotidine Injection\)](#)
[Percocet \(Oxycodone and Acetaminophen\)](#)
[Percodan \(Aspirin, Oxycodone Hydrochloride, Oxycodone Terephthalate\)](#)
[Perfluoroalkylpolyether \(PFPE\), Polytetrafluoroethylene \(PTFE\) \(Skin Exposure Paste\)](#)
[Perflutren Lipid Microsphere \(Definity\)](#)
[Perflutren Protein-Type A Microspheres \(Optison\)](#)
[Perforomist \(Formoterol Fumarate Inhalation Solution\)](#)
[Pergolide Mesylate \(Permax\)](#)
[Periactin \(Cyproheptadine\)](#)
[Perindopril Erbumine \(Aceon\)](#)
[Periochip \(Chlorhexidine\)](#)
[Periostat \(Doxycycline Hyclate\)](#)
[Peritoneal Dialysis Solution \(Dianeal PD-1\)](#)
[Peritoneal Dialysis Solution \(Dianeal PD-2\)](#)
[Permax \(Pergolide Mesylate\)](#)
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[Persantine IV \(Persantine\)](#)
[Pexeva \(Paroxetine Mesylate\)](#)

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Pf-Ph

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[Phendimetrazine Tartrate \(Phendimetrazine Tartrate\)](#)
[Phenelzine \(Nardil\)](#)
[Phenergan \(Promethazine\)](#)
[Phenergan Vc \(Promethazine HCl and Phenylephrine HCl Syrup\)](#)
[Phenergan-Codeine \(Codeine Phosphate and Promethazine HCl\)](#)
[Phenobarbital \(Phenobarbital\)](#)
[Phenoxybenzamine \(Dibenzyline\)](#)
[Phentermine \(Fastin\)](#)
[Phentermine Resin Complex \(Ionamin\)](#)
[Phentolamine Mesylate \(Phentolamine Mesylate for Injection\)](#)
[Phentolamine Mesylate for Injection \(Phentolamine Mesylate\)](#)
[Phenylephrine Hydrochloride Ophthalmic Solution \(Neo-Synephrine\)](#)
[Phenylephrine, Hydrocodone, CPM \(Histinex HC\)](#)
[Phenylpropranolamine, Dextromethorphan and Brompheniramine \(Histinex\)](#)
[Phenytoin \(Dilantin\)](#)
[PhisoHex \(Hexachlorophene\)](#)
[Phosphate Tablets \(Primaquine\)](#)
[Phospholine \(Phospholine\)](#)

[Photofrin \(Porfimer Sodium\)](#)[Physostigmine Salicylate \(injection\) \(Antilirium\)](#)[Phytonadione \(Mephyton\)](#)[↑ Back to Top](#)**Pi-Pm**[Pilocarpine \(Isopto Carpine\)](#)[Pilocarpine Hydrochloride \(Salagen\)](#)[Pilocarpine Hydrochloride Ophthalmic Gel \(Pilopine HS\)](#)[Pilopine HS \(Pilocarpine Hydrochloride Ophthalmic Gel\)](#)[Pimecrolimus Cream \(Elidel\)](#)[Pimozide \(Orap\)](#)[Pindolol \(Visken\)](#)[Pioglitazone \(Duetact\)](#)[Pioglitazone Hcl and Metformin Hcl \(Actoplus MET\)](#)[Pioglitazone hydrochloride \(Actos\)](#)[Piperacillin and Tazobactam Injection \(Zosyn\)](#)[Piperacillin and Tazobactam Pharmacy Bulk Vial \(Zosyn Injection\)](#)[Piperacillin Sodium \(Pipracil\)](#)[Pipracil \(Piperacillin Sodium\)](#)[Pirbuterol \(Maxair\)](#)[Piroxicam \(Feldene\)](#)[Pitocin \(Oxytocin Injection\)](#)[Pitressin \(Vasopressin\)](#)[Plan B \(Levonorgestrel\)](#)[Plaquenil \(Hydroxychloroquine\)](#)[Plasma-Lyte 148 \(Multiple Electrolytes Inj\)](#)[Plasma-Lyte 148d5 \(Multiple Electrolytes and Dextrose Inj\)](#)[Plasma-Lyte 56 \(Multiple Electrolytes Inj\)](#)[Plasma-Lyte 56d5 \(Multiple Electrolytes Inj\)](#)[Plasma-Lyte M and 5% Dextrose Inj \(Plasma-Lyte Md5\)](#)[Plasma-Lyte Md5 \(Plasma-Lyte M and 5% Dextrose Inj\)](#)[PlasmaLyte A \(Multiple Electrolytes Injection\)](#)[PlasmaLyte R \(Multiple Electrolytes Injection\)](#)[Plavix \(Clopidogrel Bisulfate\)](#)[Plenaxis \(Abarelix\)](#)[Plendil \(Felodipine\)](#)[Pletal \(Cilostazol\)](#)[Plexion \(Sulfacetamide\)](#)[Plicamycin \(Mithracin\)](#)[↑ Back to Top](#)**Pn-Pq**[Pneumococcal 7-valent Conjugate \(Prennar\)](#)[Pneumococcal Vaccine Polyvalent \(Pneumovax\)](#)[Pneumovax \(Pneumococcal Vaccine Polyvalent\)](#)[Podocon-25 \(Podophyllin\)](#)[Podofilox \(Condylox\)](#)[Podofilox \(Podofilox Topical Solution\)](#)[Podofilox Topical Solution \(Podofilox\)](#)[Podophyllin \(Podocon-25\)](#)[Polifeprosan 20 with Carmustine \(Gliadel\)](#)[Poliovirus Vaccine Inactivated \(Ipol\)](#)

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Pr-Pr

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[Prednisone \(Deltasone\)](#)
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Propranolol Hydrochloride and Hydrochlorothiazide (Inderide)
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Proquad (Measles Mumps Rubella Varicella Vaccine Live)
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Proscar (Finasteride)
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Prosom (Estazolam)
Prostigmin (Neostigmine)
Prostin E2 (Dinoprostone Vaginal Suppository)
Prostin VR Pediatric (Alprostadi)
Protamine (Protamines)
Protamines (Protamine)
Protein C Concentrate (Ceprotin)
Protirelin (Thyrel Trh)
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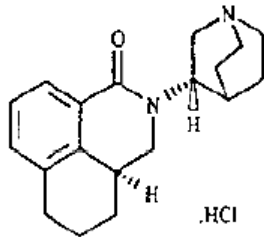
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ALOXI

(palonosetron HCl) Capsules

DRUG DESCRIPTION

ALOXI (palonosetron HCl) Capsules is an antiemetic and antinauseant agent. It is a serotonin subtype 3 (5-HT₃) receptor antagonist with a strong binding affinity for this receptor. Chemically, palonosetron hydrochloride is: (3a*S*)-2-[(*S*)-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 C₁₉H₂₄N₂O.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.

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Aloxi Capsules

Indications & Dosage

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INDICATIONS

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

DOSAGE AND ADMINISTRATION

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.

HOW SUPPLIED

Dosage Forms And Strengths

Capsules, 0.5 mg

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 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see **USP Controlled Room Temperature**].
- Protect from light.

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. Revised 08/2008. FDA Rev date: 8/22/2008

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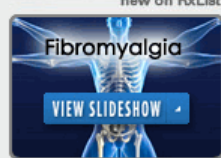
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Aloxi Capsules

Side Effects & Drug Interactions

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SIDE EFFECTS

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**.

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

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.

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Warnings & Precautions

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WARNINGS

Included as part of the **PRECAUTIONS** section.

PRECAUTIONS

Hypersensitivity

Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT₃ 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.

Patient Counseling Information

See FDA-Approved [Patient Labeling](#)

Instructions for Patients

- Patients should be instructed to read the patient insert.

Nonclinical Toxicology

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.

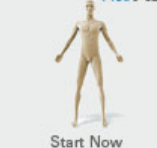
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Pregnancy

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.

Labor and Delivery

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

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.

Pediatric Use

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

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.

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](#).

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.

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.

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.

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Aloxi Capsules

Overdosage & Contraindications

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OVERDOSE

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.

CONTRAINDICATIONS

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

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Aloxi Capsules

Clinical Pharmacology

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CLINICAL PHARMACOLOGY

Mechanism of Action

Palonosetron is a 5-HT₃ 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. 5HT₃ 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-HT₃ receptors located on vagal afferents to initiate the vomiting reflex.

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 (moxifloxacin) 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.

Pharmacokinetics

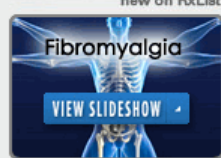
Absorption

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-∞}) 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 ± nd time to maximum concentration (T_{max}) was 5.1 ± 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).

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Table 2: Mean PK parameters¹ (± 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 ±107	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 across-study comparison		

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

Distribution

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

Metabolism

Palonosetron is eliminated by multiple routes with approximately 50% metabolized to form two primary metabolites: N-oxide-palonosetron and 6-Shydroxy- palonosetron. These metabolites each have less than 1% of the 5-HT₃ 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 [¹⁴C]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 (t_{1/2}) of palonosetron was 37 (mean ± dose of approximately 0.75 mg intravenous palonosetron, the total body clearance of palonosetron in healthy subjects was 160 SD) and renal clearance was 66.5

Special Populations

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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 12 hours in of the non-inferiority margin.

As indicated in the data above, analysis of the key secondary endpoint showed 35 mL/h/kg (mean that a single dose of ALOXI Capsules 0.5 mg was numerically similar to a 18.2 mL/h/kg. 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 024 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 024 hour interval was similar throughout the consecutively repeated cycles.

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Aloxi Capsules

Patient Information

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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)

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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°F to 86°F (15°C to 30°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 1-888-4224743, 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

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