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About DailyMed

DailyMed provides high quality information about marketed drugs. This information includes FDA approved labels (package inserts). This Web site provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling as found in medication package inserts.

Other information about prescription drugs may also be available. NLM regularly processes data files uploaded from FDA's system and provides and maintains this Web site for the public to use in accessing the information. Additional information about medicines is available on NLM's MedlinePlus Web site <http://www.nlm.nih.gov/medlineplus/medicines.html>.



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[Abraxane \(paclitaxel\) Injection, Powder, Lyophilized, For Suspension](#)
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**ALOXI (palonosetron hydrochloride) capsule, gelatin coated
[EISAI]**

**Aloxi (palonosetron hydrochloride) Solution for Intravenous
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[MGI PHARMA]**

**An-Dtpa (pentetate calcium trisodium) Injection
[CIS-US, INC.]**

**Aredia (pamidronate disodium) Injection, Powder, Lyophilized,
For Solution
[Novartis Pharmaceuticals Corporation]**

**Betadin (povidone-iodine) Solution
[Alcon Laboratories, Inc.]**

**BICILLIN L-A (penicillin g benzathine) injection, suspension
[King Pharmaceuticals, Inc.]**

**Biltricide (praziquantel) Tablet, Film Coated
[Bayer Pharmaceuticals Corporation]**

**Bontril (phendimetrazine tartrate) Capsule
[Valeant Pharmaceuticals International]**

**Bontril Pdm (phendimetrazine tartrate) Tablet
[Valeant Pharmaceuticals, Inc.]**

**Citanest Plain (prilocaine hydrochloride) Injection, Solution
Citanest Forte (prilocaine hydrochloride and epinephrine
bitartrate) Injection, Solution
[DENTSPLY Pharmaceutical]**

**Compazine (prochlorperazine maleate) Tablet, Coated
Compazine (prochlorperazine maleate) Capsule, Extended
Release
Compazine (prochlorperazine maleate) Injection, Solution
Compazine (prochlorperazine maleate) Suppository
Compazine (prochlorperazine maleate) Syrup
[GlaxoSmithKline]**

**Compro (prochlorperazine) Suppository
[Paddock Laboratories, Inc.]**

**Condylox (podofilox) Gel
[Watson Pharmaceuticals, Inc.]**

Condylox (podofilox) Solution
[Watson Pharmaceuticals, Inc.]

CUPRIMINE (penicillamine) capsule
[Aton Pharma, Inc.]

Cuprimine (penicillamine) Capsule
[Merck & Co., Inc.]

Curosurf (poractant alfa) Suspension
[DEY]

Cylert (pemoline) Tablet
Cylert Chewable (pemoline) Tablet, Chewable
[Abbott Laboratories]

Daraprim (pyrimethamine) Tablet
[GlaxoSmithKline]

Darvocet A500 (propoxyphene napsylate and acetaminophen)
Tablet, Film Coated
[Xanodyne]

Darvocet-N (propoxyphene napsylate and acetaminophen)
Tablet, Film Coated
[Xanodyne pharmaceuticals, inc.]

Darvon (propoxyphene hydrochloride) Capsule
[Xanodyne Pharmaceuticals, Inc.]

Darvon-N (propoxyphene napsylate) Tablet, Film Coated
[Xanodyne]

DEFINITY (perflutren) injection, suspension
[Bristol-Myers Squibb Medical Imaging]

Deltasone (prednisone) Tablet
[Pharmacia and Upjohn and Company]

Denavir (penciclovir) Cream
[Novartis Consumer Health, Inc.]

DERMATOP (prednicarbate) cream
[Dermik Laboratories]

Dermatop (prednicarbate) Ointment
[Dermik Laboratories]

Dibenzyline (phenoxybenzamine hydrochloride) Capsule
[WellSpring Pharmaceutical Corporation]

DILANTIN (phenytoin sodium) capsule, extended release
[Parke-Davis]

DILANTIN KAPSEALS (phenytoin sodium) capsule, extended release
[Parke-Davis]

Dilantin-125 (phenytoin) Suspension
[Parke-Davis]

Diprivan (propofol) Injection, Emulsion
[AstraZeneca Pharmaceuticals LP]

Duetact (pioglitazone hydrochloride and glimepiride) Tablet
[Takeda Pharmaceuticals America, Inc]

DUODOTE (atropine and pralidoxime chloride) kit
[Meridian Medical Technologies, Inc.]

Econopred (prednisolone acetate) Suspension
[ALCON LABORATORIES, INC.]

Econopred (prednisolone acetate) Suspension
[Alcon Laboratories, Inc.]

Elidel (pimecrolimus) Cream
[Novartis Pharmaceuticals Corporation]

Elimite (permethrin) Cream
[Allergan]

Elmiron (pentosan polysulfate sodium) Capsule
[ORTHO-McNEIL PHARMACEUTICAL, INC.]

Endometrin (progesterone) Tablet, Effervescent for Vaginal use
[Ferring Pharmaceuticals Inc.]

Feldene (piroxicam) Capsule
[Pfizer Labs]

Flo-Pred (prednisolone acetate) Suspension for Oral use
[Taro Pharmaceuticals U.S.A., Inc.]

Halflytely And Bisacodyl (polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride and bisacodyl) Kit for use
[Braintree Laboratories, Inc.]

Humatin (paromomycin sulfate) Capsule
[Monarch Pharmaceuticals, Inc.]

Inderal (propranolol hydrochloride) Tablet
[Wyeth Pharmaceuticals, Inc.]

Inderal La (propranolol hydrochloride) Capsule, Extended Release
[Wyeth Pharmaceuticals, Inc.]

INDERIDE (propranolol hydrochloride and hydrochlorothiazide) tablet
[Wyeth Pharmaceuticals, Inc.]

Innopran XI (propranolol hydrochloride) Capsule, Extended Release
[Reliant Pharmaceuticals, Inc.]

INVEGA (paliperidone) tablet, extended release
[Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.]

Ionamin (phentermine) Capsule
[Celltech Pharmaceuticals, Inc.]

K-Dur (potassium chloride) Tablet, Extended Release
[Key Pharmaceuticals, Inc.]

K-Tab (potassium chloride) Tablet, Film Coated, Extended Release
[Abbott Laboratories]

Kemadrin (procyclidine hydrochloride) Tablet
[Monarch Pharmaceuticals, Inc.]

KEPIVANCE (palifermin) injection
[Amgen]

Klor-Con (potassium chloride) Tablet, Extended Release
[UPSHER-SMITH LABORATORIES, INC.]

**Klor-Con M (potassium chloride) Tablet, Extended Release
[UPSHER-SMITH LABORATORIES, INC.]**

**Klotrix (potassium chloride) Tablet, Film Coated, Extended Release
[Bristol-Myers Squibb Company]**

**Levatol (penbutolol sulfate) Tablet
[SRZ Properties, Inc.]**

**Lyrica (pregabalin) Capsule for Oral use - CV
[Pfizer]**

**Maxair (pirbuterol acetate) Aerosol, Metered
[3M Pharmaceuticals]**

**Maxair (pirbuterol acetate) Aerosol, Metered
[3M Pharmaceuticals]**

**MEPHYTON (phytonadione) tablet
[Aton Pharma, Inc.]**

**Mephyton (phytonadione) Tablet
[Merck & Co., Inc.]**

**Mestinon (pyridostigmine bromide) Syrup
Mestinon (pyridostigmine bromide) Tablet
Mestinon (pyridostigmine bromide) Tablet, Extended Release
[Valeant Pharmaceuticals, Inc.]**

**Micro-K Extencaps (potassium chloride) Capsule, Extended Release
Micro-K 10 Extencaps (potassium chloride) Capsule, Extended Release
[KV Pharmaceuticals]**

**Minipress (prazosin hydrochloride) Capsule
[Pfizer Labs]**

**Minizide (prazosin hydrochloride and polythiazide) Capsule
[Pfizer Labs]**

**MIRAPEX (pramipexole dihydrochloride) tablet
[Boehringer Ingelheim Pharmaceuticals, Inc.]**

**MOVIPREP (polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid) solution
[Salix Pharmaceuticals, Inc.]**

MOZOBIL (plerixafor) solution
[Genzyme Corporation]

Mysoline (primidone) Tablet
[Valeant Pharmaceuticals North America]

Nardil (phenelzine sulfate) Tablet, Film Coated
[Pfizer Inc.]

Nembutal Sodium (pentobarbital sodium) Injection
[OVATION Pharmaceuticals, Inc.]

Neulasta (pegfilgrastim) Injection, Solution
[Amgen Manufacturing, Limited]

Nipent (pentostatin) Injection, Powder, Lyophilized, For Solution
[Hospira, Inc.]

Novocain (procaine hydrochloride) Injection, Solution
[Hospira, Inc.]

Novocaine (procaine hydrochloride) Injection, Solution
[Hospira, Inc.]

Noxafil (posaconazole) Suspension
[Schering-Plough Corporation]

Omnipred (prednisolone acetate) Suspension
[Alcon Laboratories, INC.]

**Oncaspar (pegaspargase) Injection, Solution for Intramuscular
and Intravenous use**
[ENZON PHARMACEUTICALS, INC.]

Onxol (paclitaxel) Injection, Solution, Concentrate
[IVAX Research, Inc.]

Ophthetic (proparacaine hydrochloride) Solution
[Allergan, Inc.]

**Oraverse (phentolamine mesylate) Injection, Solution for
Submucosal use**
[Novalar Pharmaceuticals]

Pacerone (amiodarone hydrochloride) Tablet
[UPSHER-SMITH LABORATORIES, INC.]

Paclitaxel (paclitaxel) Injection, Solution
[Mayne Pharma (USA) Inc.]

Paclitaxel (paclitaxel) Solution
[Bedford Laboratories]

PACLITAXEL injection, solution
[Teva Parenteral Medicines]

Palladone (hydromorphone hydrochloride) Capsule, Extended Release
[Purdue Pharma L.P.]

Pamelor (nortriptyline hydrochloride) Capsule
Pamelor (nortriptyline hydrochloride) Solution
[Mallinckrodt Inc.]

Pamidronate Disodium (pamidronate disodium) Injection, Solution
Pamidronate Disodium (pamidronate disodium) Injection, Powder, Lyophilized, For Solution
[Bedford Laboratories]

Pamidronate Disodium (pamidronate disodium) Solution
[Barr Laboratories, Inc.]

Pamidronate Disodium (pamidronate disodium) Solution
[Mayne Pharma (USA) Inc.]

PAMIDRONATE DISODIUM injection
PAMIDRONATE DISODIUM (pamidronate disodium injection) injection
[Akorn-Strides, LLC]

Pamine (methscopolamine bromide) Tablet
Pamine Forte (methscopolamine bromide) Tablet
[Kenwood Therapeutics, a division of Bradley Pharmaceuticals, Inc]

Pancuronium Bromide (pancuronium bromide) Injection, Solution
[HOSPIRA, INC.]

Pandel (hydrocortisone probutate) Cream
[PharmaDerm, A division of Nycomed US Inc.]

Panixine Disperdose (cephalexin) Tablet, Soluble
[Ranbaxy Laboratories, Inc.]

Panretin (alitretinoin) Gel
[Ligand Pharmaceuticals Incorporated]

Pantoprazole Sodium (pantoprazole sodium) Tablet, Delayed Release
[Wyeth Pharmaceuticals, Inc.]

Parafon Forte (chlorzoxazone) Tablet
[ORTHO-McNEIL PHARMACEUTICAL, INC.]

Paragard T380a (copper) Intrauterine Device
[FEI Products LLC]

Paraplatin (carboplatin) Injection, Powder, Lyophilized, For Solution
[Bristol-Myers Squibb]

Paraplatin (carboplatin) Injection, Solution
[Bristol-Myers Squibb]

Parcopa (carbidopa and levodopa) Tablet, Orally Disintegrating
[Schwarz Pharma]

Paremyd (hydroxyamphetamine hydrobromide and tropicamide) Solution
[Akorn, Inc.]

Parnate (tranylcypromine sulfate) Tablet, Film Coated
[GlaxoSmithKline]

Paromomycin Sulfate (paromomycin sulfate) Capsule
[CARACO PHARMACEUTICAL LABORATORIES, LTD.]

Paromomycin Sulfate (paromomycin sulfate) Capsule, Gelatin Coated
[X-Gen Pharmaceuticals Inc.]

Paroxetine (paroxetine hydrochloride) Tablet
[Apotex Corp.]

PAROXETINE (paroxetine hydrochloride) tablet
[Aurobindo Pharma Limited]

Paroxetine (paroxetine hydrochloride) Tablet
[CARACO PHARMACEUTICAL LABORATORIES, LTD.]

Paroxetine (paroxetine hydrochloride) Tablet, Film Coated
[ALPHAPHARM PTY. LTD.]

**Paroxetine (paroxetine hydrochloride) Tablet, Film Coated
[Teva Pharmaceuticals USA]**

**Paroxetine (paroxetine hydrochloride) Tablet, Film Coated
[TEVA PHARMACEUTICALS USA]**

**Paroxetine Hydrochloride (paroxetine hydrochloride)
Suspension
[Apotex Corp.]**

**Paroxetine Hydrochloride (paroxetine hydrochloride) Tablet,
Film Coated, Extended Release
[Mylan Pharmaceuticals Inc.]**

**Pataday (olopatadine hydrochloride) Solution/ Drops
[Alcon]**

**Patanase (olopatadine hydrochloride) Solution for Nasal use
[ALCON LABORATORIES, INC.]**

**Patanol (olopatadine hydrochloride) Solution / Drops
[Alcon Laboratories]**

**PAXIL (paroxetine hydrochloride) tablet
PAXIL (paroxetine hydrochloride) suspension
[GlaxoSmithKline]**

**PAXIL CR (paroxetine hydrochloride) tablet, film coated,
extended release
[GlaxoSmithKline]**

**PCE (erythromycin) tablet
[Abbott Laboratories]**

**Pediotic (neomycin sulfate, polymyxin b sulfate and
hydrocortisone acetate) Suspension
[Monarch Pharmaceuticals, Inc.,]**

**Peganone (ethotoin) Tablet
[Ovation Pharmaceuticals, Inc.]**

**Pegasys (peginterferon alfa-2a) Injection, Solution
[Roche Pharmaceuticals]**

**Penicillin G Potassium (penicillin g) Injection, Solution
[Baxter Healthcare Corporation]**

**Penicillin G Procaine (penicillin g and procaine) Injection
[Monarch Pharmaceuticals, Inc.]**

**Penicillin G Sodium (penicillin g sodium) Injection, Powder, For
Solution
[Sandoz Inc.]**

**Penicillin V Potassium (penicillin v potassium) Powder, For
Solution
[Bristol-Myers Squibb Company]**

**Penicillin V Potassium (penicillin v potassium) Tablet
Penicillin V Potassium (penicillin v potassium) Powder, For
Solution
[Teva Pharmaceuticals USA]**

**Penicillin V Potassium (penicillin v potassium) Tablet
[Sandoz Inc.]**

**Penlac (ciclopirox) Solution
[Dermik Laboratories]**

**Pentasa (mesalamine) Capsule
[Shire US Inc.]**

**Pentazocine And Naloxone (pentazocine hydrochloride and
naloxone hydrochloride) Tablet
[Watson Laboratories, Inc.]**

**Pentazocine And Naloxone Hydrochlorides (pentazocine
hydrochloride and naloxone hydrochloride) Tablet
[Actavis Totowa LLC]**

**Pentazocine Hcl And Acetaminophen (pentazocine hydrochloride
and acetaminophen) Tablet
[Watson Laboratories, Inc.]**

**Pentetate Calcium Trisodium (pentetate calcium trisodium)
Injection, Solution, Concentrate
[Hameln Pharmaceuticals]**

**Pentetate Zinc Trisodium (pentetate zinc trisodium) Injection,
Solution, Concentrate
[Hameln Pharmaceuticals]**

**PENTOSTATIN injection, powder, lyophilized, for solution
[Bedford Laboratories]**

**Pentoxifylline (pentoxifylline) Tablet, Extended Release
[TEVA PHARMACEUTICALS USA]**

Pentoxifylline (pentoxifylline) Tablet, Film Coated, Extended Release
[Mylan Pharmaceuticals Inc.]

Pentoxil (pentoxifylline) Tablet, Film Coated, Extended Release
[UPsher-Smith Laboratories, Inc.]

Pepcid (famotidine) Injection, Solution
Pepcid (famotidine) Injection, Solution, Concentrate
[Merck & Co., Inc.]

Pepcid (famotidine) Powder, For Suspension
[Salix Pharmaceuticals, Inc.]

PEPCID (famotidine) tablet, film coated
[Merck & Co., Inc.]

Perforomist (formoterol fumarate dihydrate) Solution for Respiratory (Inhalation) use
[Dey, L.P.]

Pergolide Mesylate (pergolide mesylate) Tablet
[IVAX Pharmaceuticals, Inc.]

Pergolide Mesylate (pergolide mesylate) Tablet
[Par Pharmaceutical Inc.]

PERIDEX (chlorhexidine gluconate) liquid
[3M]

Periogard (chlorhexidine gluconate) Liquid
[Colgate Oral Pharmaceuticals Inc.]

Periostat (doxycycline hyclate) Tablet
[CollaGenex Pharmaceuticals, Inc.]

Permapen (penicillin G benzathine) Injection, Suspension
[Roerig]

Permax (pergolide) Tablet
[Valeant Pharmaceuticals, Inc.]

Permethrin (permethrin) Cream
[Actavis Mid Atlantic LLC]

Permethrin (permethrin) Cream
[Perrigo New York, Inc.]

**Perphenazine (perphenazine) Tablet, Film Coated
[IVAX Pharmaceuticals, Inc.]**

**Perphenazine (perphenazine) Tablet, Film Coated
[Sandoz Inc.]**

**Perphenazine (perphenazine) Tablet, Sugar Coated
[Qualitest Pharmaceuticals]**

**PERPHENAZINE AND AMITRIPTYLINE HYDROCHLORIDE tablet,
film coated
[Mylan Pharmaceuticals Inc.]**

**Persantine (dipyridamole) Tablet
[Boehringer Ingelheim]**

**PEXEVA (paroxetine mesylate) tablet, film coated
[Noven Therapeutics, LLC]**

**Pfizerpen (penicillin g potassium) Powder, For Solution
[Roerig]**

**PHENADOZ (promethazine hydrochloride) suppository
[Paddock Laboratories, Inc.]**

**Phendimetrazine Tartrate (phendimetrazine tartrate) Capsule
[Sandoz Inc.]**

**Phendimetrazine Tartrate (phendimetrazine tartrate) Tablet
[MIKART, INC.]**

**Phenergan (promethazine hydrochloride) Injection, Solution
[Baxter Healthcare Corporation]**

**Phenergan (promethazine hydrochloride) Tablet
Phenergan (promethazine hydrochloride) Suppository
[Wyeth Pharmaceuticals Inc.]**

**Phermine (phentermine hydrochloride) Tablet
[Actavis Elizabeth LLC]**

**Phermine Hydrochloride (phentermine hydrochloride)
Capsule
Phermine Hydrochloride (phentermine hydrochloride) Tablet
[Actavis Totowa LLC]**

**Phermine Hydrochloride (phentermine hydrochloride)
Capsule
[MUTUAL PHARMACEUTICAL CO., INC.]**

**Phentermine Hydrochloride (phentermine hydrochloride) Tablet
[Qualitest Pharmaceuticals]**

**PHENTERMINE HYDROCHLORIDE capsule
[Lannett Company, Inc.]**

**PHENTERMINE HYDROCHLORIDE tablet
[Lannett Company, Inc.]**

**Phentolamine Mesylate (phentolamine mesylate) Injection,
Powder, For Solution
[Bedford Laboratories]**

**Phenytoin (phenytoin) Suspension
[Morton Grove Pharmaceuticals, Inc.]**

**Phenytoin (phenytoin) Suspension
[Taro Pharmaceuticals U.S.A., Inc.]**

**Phenytoin Sodium (phenytoin sodium) Capsule
[Mylan Pharmaceuticals Inc.]**

**Phenytoin Sodium (phenytoin sodium) Injection, Solution
[Baxter Healthcare Corporation]**

**Phenytoin Sodium (phenytoin sodium) Injection, Solution
[HOSPIRA, INC.]**

**Phenytoin Sodium (phenytoin sodium) Injection, Solution
[Hospira]**

**PHENYTOIN SODIUM capsule, extended release
[Taro Pharmaceuticals U.S.A., Inc.]**

**PHENYTOIN suspension
[Actavis Mid Atlantic LLC]**

**Phisohex (hexachlorophene) Emulsion
[Sanofi-Synthelabo Inc.]**

**Phoslo (calcium acetate) Capsule
[Fresenius Medical Care North America]**

**Phoslo (calcium acetate) Tablet
[Nabi Biopharmaceuticals]**

Phosphocol P 32 (chromic phosphate, p-32) Injection, Suspension
[Mallinckrodt Inc.]

Phospholine Iodide (echothiophate iodide)
[Wyeth Pharmaceuticals Inc.]

Phosphotec (sodium pyrophosphate and stannous fluoride) Injection, Powder, Lyophilized, For Solution
[Bracco Diagnostics, Inc.]

Photofrin (porfimer sodium) Injection, Powder, For Solution
[Axcan Scandipharm Inc.]

Phrenilin (butalbital and acetaminophen) Tablet
Phrenilin Forte (butalbital and acetaminophen) Capsule
[Valeant Pharmaceuticals North America]

Phrenilin (butalbital, acetaminophen, caffeine, and codeine phosphate) Capsule
[Valeant Pharmaceuticals North America]

PHYSIOLYTE (sodium chloride, sodium gluconate, sodium acetate, potassium chloride, and magnesium chloride) injection
[B. Braun Medical Inc.]

Physiosol (sodium chloride, sodium acetate anhydrous, sodium gluconate, potassium chloride, and magnesium chloride) Irrigant
[Hospira, Inc.]

Physiosol (sodium chloride, sodium acetate, sodium gluconate, potassium chloride and magnesium chloride) Irrigant
[Hospira]

Phytonadione (phytonadione) Injection, Emulsion
[International Medication System, Limited]

Pilocarpine Hydrochloride (pilocarpine hydrochloride) Tablet
[Global Pharmaceuticals]

Pilocarpine Hydrochloride (pilocarpine hydrochloride) Tablet
[Roxane]

Pilocarpine Hydrochloride (pilocarpine hydrochloride) Tablet, Film Coated
[Activis Elizabeth LLC]

Pilocarpine Hydrochloride (pilocarpine hydrochloride) Tablet, Film Coated
[Lannett Company, Inc.]

Pilocarpine Hydrochloride (pilocarpine hydrochloride) Tablet, Film Coated
[Sandoz Inc.]

Pilopine Hs (pilocarpine hydrochloride) Gel
[ALCON LABORATORIES, INC.]

Pipracil (piperacillin sodium) Injection, Powder, Lyophilized, For Solution
[Wyeth Pharmaceuticals, Inc.]

Piroxicam (piroxicam) Capsule
[GENPHARM INC.]

Piroxicam (piroxicam) Capsule
[Mylan Pharmaceuticals Inc.]

Piroxicam (piroxicam) Capsule
[TEVA PHARMACEUTICALS USA]

Pitocin (oxytocin) Injection
[King Pharmaceuticals, Inc.]

Pitocin (oxytocin) Injection
[Watson Laboratories, Inc.]

Plan B (levonorgestrel) Tablet
[Duramed Pharmaceuticals, Inc.]

Plaquenil (hydroxychloroquine sulfate) Tablet, Film Coated
[sanofi-aventis U.S. LLC]

Plasma-Lyte 148 (sodium chloride, sodium gluconate, sodium acetate, potassium chloride and magnesium chloride) Injection, Solution
[Baxter Healthcare Corporation]

Plasma-Lyte 148 And Dextrose (sodium chloride, potassium chloride, calcium chloride, sodium gluconate, sodium acetate and dextrose) Injection, Solution
[Baxter Healthcare Corporation]

Plasma-Lyte 56 (sodium chloride, potassium acetate, magnesium acetate tetrahydrate) Injection
[Baxter Healthcare Corporation]

Plasma-Lyte 56 And Dextrose (sodium chloride, potassium acetate, magnesium acetate and dextrose) Injection, Solution

[Baxter Healthcare Corporation]

Plasma-Lyte M And Dextrose (sodium chloride, potassium chloride, magnesium chloride, calcium chloride, sodium acetate, sodium lactate and dextrose) Injection, Solution

[Baxter Healthcare Corporation]

Plasma-Lyte R (sodium chloride, potassium chloride, magnesium chloride, calcium chloride, sodium acetate and sodium lactate) Injection, Solution

[Baxter Healthcare Corporation]

Platinol (cisplatin) Injection, Powder, For Solution

[Bristol-Myers Squibb Company]

Plavix (clopidogrel bisulfate) Tablet, Film Coated

[Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership]

PLEGISOL (calcium chloride, magnesium chloride, potassium chloride, and sodium chloride) injection, solution

[Hospira, Inc.]

Plendil (felodipine) Tablet, Extended Release

[AstraZeneca LP]

Pletal (cilostazol) Tablet

[OTSUKA AMERICA PHARMACEUTICAL, INC.]

Pliaglis (lidocaine and tetracaine) Cream

[GALDERMA LABORATORIES, L.P.]

Podofilox (podofilox) Solution

[Paddock Laboratories, Inc.]

Podofilox (podofilox) Solution

[Watson Laboratories, Inc.]

Polocaine (mepivacaine hydrochloride) Injection

Polocaine With Levonordefrin (mepivacaine hydrochloride and levonordefrin) Injection

[DENTSPLY Pharmaceutical]

Polocaine (mepivacaine hydrochloride) Injection

[AstraZeneca]

Poly-Pred (prednisolone acetate, neomycin sulfate, polymyxin b sulfate) Suspension

[Allergan, Inc.]

POLYETHYLENE GLYCOL 3350 powder, for solution

[Paddock Laboratories, Inc]

Polymyxin B (polymyxin b sulfate) Injection, Powder, For Solution
[Bedford Laboratories]

Polymyxin B (polymyxin b sulfate) Injection, Powder, For Solution
[Bedford Laboratories]

Polymyxin B (polymyxin b sulfate) Injection, Powder, Lyophilized, For Solution
[X-Gen Pharmaceuticals Inc.]

Polymyxin B Sulfate And Trimethoprim (polymyxin b sulfate and trimethoprim sulfate) Solution / Drops
[Bausch & Lomb Incorporated]

Polymyxin B Sulfate And Trimethoprim (polymyxin b sulfate and trimethoprim) Solution
[Falcon Pharmaceuticals, Ltd]

Polysporin (bacitracin zinc and polymyxin b sulfate) Ointment
[Monarch Pharmaceuticals, Inc.]

Polytrim (polymyxin b sulfate and trimethoprim sulfate) Solution
[Allergan, Inc.]

Ponstel (mefenamic acid) Capsule
[Sciele Pharma Inc.]

Potassium Acetate (potassium acetate) Injection, Solution, Concentrate
[Hospira, Inc.]

Potassium Chloride (potassium chloride) Capsule, Extended Release
[ETHEX Corporation]

Potassium Chloride (potassium chloride) Capsule, Extended Release
[ETHEX]

Potassium Chloride (potassium chloride) Injection
[Baxter Healthcare Corporation]

Potassium Chloride (potassium chloride) Injection, Solution
[HOSPIRA, INC.]

Potassium Chloride (potassium chloride) Injection, Solution, Concentrate
[Baxter Healthcare Corporation]



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ALOXI (palonosetron hydrochloride) capsule, gelatin coated [EISAI]

RxNorm Names

[Review RxNorm Normal Forms](#)

Drug Label Sections

Description	Clinical Pharmacology	Indications & Usage
Contraindications	Warnings	Precautions
Overdosage	Dosage & Administration	How Supplied
Patient Counseling Information	Supplemental Patient Material	
Boxed Warning	Patient Package Insert	Highlights
Full Table of Contents	Medication Guide	

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

ALOXI (palonosetron hydrochloride) capsule, gelatin coated for oral use
 Initial U.S. Approval: 2003

INDICATIONS AND USAGE

ALOXI Capsules, a serotonin subtype 3 (5-HT₃) 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-HT₃ receptor antagonists (5.1)

ADVERSE REACTIONS

No adverse reactions have been reported at an incidence of $\geq 5\%$ 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: 09/2008

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

3 DOSAGE FORMS AND STRENGTHS

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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-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.

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 $\geq 2\%$ of patients from two clinical trials.

Table 1: Adverse Reactions $\geq 2\%$ 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 $\geq 1\%$. 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 functional 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 $\mu\text{g}/\text{kg}$. 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

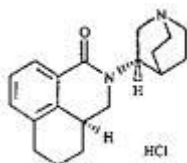
There is no known antidote to ALOXI. Overdose should be managed with supportive care.

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-HT₃) receptor antagonist with a strong binding affinity for this receptor. Chemically, palonosetron hydrochloride is: (3aS)-2-[(S)-1-Azabicyclo [2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1H-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.

12 CLINICAL PHARMACOLOGY

12.1 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. 5-HT₃ 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.

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 (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.

12.3 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 ($AUC_{0-\infty}$) were dose proportional over the dose range of 3.0 to 80 $\mu\text{g}/\text{kg}$ 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 ± 0.17 ng/mL (mean \pm 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 parameters¹ (\pm 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 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-S-hydroxy-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 ± 12 hours (mean ± SD), and in cancer patients, t_{1/2} 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 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [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°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 1-888-422-4743, 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

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201228

Revised 08/2008

ALOXI

palonosetron hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	62856- 799
Route of Administration	ORAL	DEA Schedule	

INGREDIENTS

Name (Active Moiety)	Type	Strength
palonosetron hydrochloride (palonosetron)	Active	.5 MILLIGRAM In 1 CAPSULE
mono- and di-glycerides of capryl/capric acid	Inactive	
glycerin	Inactive	
polyglyceryl oleate	Inactive	
water	Inactive	
butylated hydroxyanisole	Inactive	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	3mm
Flavor		Imprint Code	
Contains			
Coating	true	Symbol	false

Packaging

# NDC	Package Description	Multilevel Packaging
1 62856-799-05	5 CAPSULE In 1 BOTTLE	None

Revised: 09/2008



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