

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrALOXI®
palonosetron hydrochloride injection

Read this carefully before you start taking ALOXI and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ALOXI.

What is ALOXI used for?

ALOXI is used in:

- adults,
 - adolescents and
 - children over 2 years of age
- to prevent nausea and vomiting that may happen after taking certain anti-cancer medicines (chemotherapy).

How does ALOXI work?

ALOXI is a medicine called an “antiemetic”. ALOXI blocks the action of the natural substance called serotonin which can cause nausea and vomiting.

What are the ingredients in ALOXI?

Medicinal ingredients: Palonosetron hydrochloride

Non-medicinal ingredients: Citrate buffer in water, disodium edetate, mannitol

ALOXI comes in the following dosage forms:

ALOXI is supplied as a single-use, sterile, clear, colorless solution in glass vials. Each 5 ml vial contains 0.25 mg palonosetron (as palonosetron hydrochloride).

Do not use ALOXI if:

- you are allergic to palonosetron hydrochloride or any other ingredients in ALOXI injection.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALOXI. Talk about any health conditions or problems you may have, including if you:

- you have any heart disorder, including an irregular heartbeat, prolongation of the QT interval or a family history of QT prolongation or sudden cardiac death at less than 50 years of age.
- you have low levels of potassium or magnesium.
- you have high blood pressure.
- you have liver or kidney problems.
- you have acute bowel obstruction or a history of repeated constipation.
- you are pregnant or are planning to become pregnant.
- you are breast-feeding or plan to breast-feed.
- you are allergic to other 5-HT₃ receptor antagonists such as ondansetron, dolasetron, or granisetron.

Other warnings you should know about:

Serotonin Syndrome:

A rare but potentially life-threatening reaction that can occur with “antiemetic” medicines such as ALOXI. It can cause serious changes in how your brain, muscles and digestive system work.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

The reaction is more likely to occur if you also take certain other medications or herbal products. Be sure to tell your healthcare professional all the medicines and natural health products (such as St. John’s Wort) you are taking.

ALOXI may cause a severe allergic reaction. Symptoms include swelling of the face, lips or tongue, difficulty breathing, rash, or fainting.

ALOXI is not intended for people less than 2 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take ALOXI:

- Your doctor will inject ALOXI into your vein approximately 30 minutes before the start of your chemotherapy.

Usual dose:

Adults

- Your doctor will give 0.25 mg of ALOXI by injection into your vein over 30 seconds and about 30 minutes before you get your anti-cancer medicine (chemotherapy).

Children and Adolescents (aged 2 to 17 years)

- The dose of ALOXI depends on your body weight. Your doctor will use your weight to decide your dose and slowly inject the medicine into your vein 30 minutes before you get your anti-cancer medicine (chemotherapy).

Overdose:

If you think you have taken too much ALOXI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ALOXI?

These are not all the possible side effects you may feel when taking ALOXI. If you experience any side effects not listed here, contact your healthcare professional.

Common: headache, constipation, diarrhea, dizziness

Uncommon: tiredness (fatigue), abdominal pain, trouble sleeping (insomnia), changes in heart rate or palpitations, dehydration, infusion site reactions such as redness or pain, jerky body movements, coughing or shortness of breath, nosebleed, itchy skin or rash.

Tell your health professional about any side effect that bothers you or that does not go away.

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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Headache	✓		
Constipation	✓		
Diarrhea	✓		
Dizziness	✓		
UNCOMMON Fatigue	✓		
Abdominal Pain		✓	
Insomnia (trouble sleeping)	✓		
RARE Allergic reaction (swelling of the lips, face, tongue or throat, difficulty in breathing, rash, hives)			✓
Serotonin Syndrome (fever, sweating, shivering, diarrhea, nausea, vomiting; muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination; fast heartbeat, changes in blood pressure; confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 20 to 25°C; excursions permitted from 15 to 30°C.
- Protect from light.
- Keep out of the reach and sight of children.

If you want more information about ALOXI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.elvium.ca, or by calling 1-833-744-0005.

This leaflet was prepared by Elvium Life Sciences, Pickering, ON L1W 3W8.

Last Revised September 4, 2020

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Pr**ALOXI**[®]
palonosetron hydrochloride capsules

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What is ALOXI used for?

- To prevent nausea and vomiting in adults after taking certain anti-cancer medicines (chemotherapy).

How does ALOXI work?

ALOXI is a medicine called an “antiemetic”. ALOXI blocks the action of the natural substance called serotonin which can cause nausea and vomiting.

What are the ingredients in ALOXI?

Medicinal ingredients: Palonosetron hydrochloride

Non-medicinal ingredients: Black printing ink, butylated hydroxyanisole, gelatin, glycerin, monoglycerides and diglycerides of capryl/capric acid, polyglyceryl oleate, sorbitol, titanium dioxide, water. May contain traces of medium chain triglyceride and lecithin.

ALOXI comes in the following dosage forms:

ALOXI is available in light beige opaque soft gelatine capsules. Each capsule contains 0.5 mg palonosetron (as palonosetron hydrochloride).

Do not use ALOXI if:

- you are allergic to palonosetron hydrochloride or any other ingredients in ALOXI capsules.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALOXI. Talk about any health conditions or problems you may have, including if you:

- you have any heart disorder, including an irregular heartbeat, prolongation of the QT interval or a family history of QT prolongation or sudden cardiac death at less than 50 years of age.
- you have low levels of potassium or magnesium.
- you have high blood pressure.
- you have liver or kidney problems.
- you have acute bowel obstruction or a history of repeated constipation.
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The reaction is more likely to occur if you also take certain other medications or herbal products. Be sure to tell your healthcare professional all the medicines and natural health products (such as St. John’s Wort) you are taking.

ALOXI may cause severe allergic reaction. Symptoms include swelling of the face, lips or tongue, difficulty breathing, rash, or fainting.

Do not take ALOXI if you are less than 18 years.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take ALOXI:

- Take one capsule by mouth one hour before the start of chemotherapy
- ALOXI can be taken with or without food.

Usual dose:

Adults

- Take one capsule (0.5 mg) by mouth one hour before the start of anti-cancer medicine (chemotherapy).

Overdose:

If you think you have taken too much ALOXI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ALOXI?

These are not all the possible side effects you may feel when taking ALOXI. If you experience any side effects not listed here, contact your healthcare professional.

Common: headache, constipation

Uncommon: tiredness (fatigue)

Tell your health professional about any side effect that bothers you or that does not go away.

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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Headache	✓		
UNCOMMON Fatigue	✓		
Constipation	✓		
RARE Allergic reaction (swelling of the lips, face, tongue or throat, difficulty in breathing, rash, hives)			✓
Serotonin Syndrome (fever, sweating, shivering, diarrhea, nausea, vomiting; muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination; fast heartbeat, changes in blood pressure; confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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