

28 JUNE 2005 FINAL VERSION

Patient Information

ALOXI™ (Ah-lock-see)

Palonosetron HCl injection

Read the Patient Information that comes with ALOXI before your treatment with ALOXI and each time you get ALOXI. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have questions about ALOXI, ask your doctor or pharmacist.

What is ALOXI?

ALOXI is a medicine called an “antiemetic.” ALOXI is used in adults to help prevent the nausea and vomiting that happens:

- right away *with certain anti-cancer medicines (chemotherapy)*
- or later with certain anti-cancer medicines

What is ALOXI used for?

ALOXI is used to prevent nausea and vomiting that may happen:

- soon after taking certain anti-cancer medicines
- later after taking certain anti-cancer medicines

Who should not take ALOXI?

Do not take ALOXI if you are allergic to any of the ingredients in ALOXI. The active ingredient is palonosetron hydrochloride. See the end of this leaflet for a complete list of ingredients in ALOXI.

ALOXI has not been studied in children under 18 years of age.

What should I tell my doctor before using ALOXI?

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

- **have heart problems** including a problem called “congenital QT syndrome”
- **have low potassium in your blood**
- **have low magnesium in your blood**
- **are pregnant.** It is not known if ALOXI may harm your unborn baby. You and your doctor should decide if ALOXI is right for you.
- **are breastfeeding.** It is not known if ALOXI passes into your milk and if it can harm your baby. You should choose to either take ALOXI or breastfeed, but not both.

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. ALOXI should be given with caution in patients who may be taking other medicines that have caused, or may cause, severe heart beat changes.

Especially, tell your doctor if you take:

- “water pills” (diuretics)
- medicine to control your heartbeat (anti-arrhythmics)
- anthracycline (an anti-cancer medicine)

How should I use ALOXI?

ALOXI is given in your vein by IV (intravenous) injection. It is only given to you by a healthcare provider in a hospital or clinic. ALOXI is usually injected into your vein about 30 minutes before you get your anti-cancer medicine (chemotherapy).

What are the possible side effects of ALOXI?

ALOXI should be given with caution in patients who have or may develop severe heart beat changes from QT prolongation. This can happen in people who have certain heart or other medical problems or who take certain medicines.

The most common side effects of ALOXI are headache and constipation. Diarrhea and dizziness have also been observed.

These are not all the side effects from ALOXI. For more information ask your doctor or pharmacist.

General information about ALOXI

Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. ALOXI was prescribed for your medical condition.

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. You can also visit the ALOXI web site at www.ALOXI.com. Or visit www.ManageCINV.com. This is a web site for patients with nausea and vomiting from anti-cancer medicines.

What are the ingredients in ALOXI?

Active ingredient: palonosetron hydrochloride

Inactive ingredients: mannitol, disodium edetate, and citrate buffer in water

Rx Only

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