

ALOXI®

Palonosetron 250 microgram per 5 mL solution for injection; Palonosetron 75 microgram per 1.5 mL solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALOXI. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What ALOXI is used for

This medicine belongs to a group of medicines known as serotonin (5-HT₃) antagonists and is a colourless solution for injection into a vein.

It is used for the prevention of nausea and vomiting that happens:

- with cancer chemotherapy
- up to 24 hours while recovering from anaesthesia after surgery.

Your doctor, however, may prescribe this medicine for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you are given ALOXI

When you must not be given it

Do not use this medicine if you have an allergy to palonosetron or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin

ALOXI should not be used to prevent or treat nausea and vomiting in the days following chemotherapy if not associated with another chemotherapy administration.

Before you are given it

Your doctor must know about all of the following before you are given this medicine.

Tell your doctor or pharmacist if you have allergies to:

- **any medicines, in particular if you have had an allergic reaction to another medicine for nausea or vomiting**
- **any other substances, such as foods, preservatives or dyes.**

If you are pregnant or think you might be, your doctor will not use this medicine unless it is clearly necessary as it is not known whether it will cause any harmful effects when used during

pregnancy. You should always ask your doctor or pharmacist for advice before using any medicine if you are pregnant or think you might be.

It is not known if this medicine is found in breast milk. You should ask your doctor or pharmacist for advice before using it if you are breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given this medicine.

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when being given this medicine with other medicines.

How ALOXI is given

This medicine is given as an injection into a vein. A doctor or nurse will normally inject it

- about 30 minutes before the start of chemotherapy or
- right before anaesthesia for surgery.

Your doctor will decide how much of this medicine you will be given and for how long.

ALOXI is intended for single use in one patient.

Overdose

As this medicine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given it, tell your doctor immediately.

While you are using ALOXI

Things you must do

If the medicine starts to upset you or your symptoms become worse, tell your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with this medicine.

Tell your doctor if you become pregnant during treatment with this medicine.

Things to be careful of

It is not known if this medicine has any effect on your ability to drive or use machines. You should be certain that you are able to drive and operate machines safely before you try.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following common side effects may occur.

- Headache
- Dizziness
- Constipation
- Diarrhoea

Tell your doctor, nurse or pharmacist if you notice any of the above reactions and they worry you.

The following uncommon side effects may also occur.

- Loss of appetite
- Anxiety or euphoria
- Sleep disturbances
- Change of sensation in your limbs
- Visual or hearing disturbances
- Motion sickness
- Change in heart rate
- Prominent or discoloured veins
- Hiccups, flatulence or dry mouth
- Upset stomach or stomach pain
- Rash
- Joint pain
- Difficulty passing water
- Weakness or tiredness
- Fever or a flu-like illness

You should tell your doctor if you notice any of the above effects.

Your doctor will tell you if the following uncommon side effects occur.

- Changes in the amounts of certain substances in your blood or urine
- Changes in your blood pressure

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Storage

Keep out of the reach and sight of children.

Store below 25°C.

Store in the original container.

Keep the container in the outer carton in order to protect from light. Do not use this medicine if the expiry date printed on the pack has passed.

Product description

What it looks like

This medicine is a colourless solution.

It is supplied in a pack of one glass vial, which contains 5 mL of the solution.

It is supplied in a pack of 5 glass vials, which each contain 1.5 mL of the solution.

Each vial contains enough for one dose.

Ingredients

Active ingredient:

Palonosetron (as the hydrochloride)

Inactive ingredients

- Mannitol
- Disodium edetate
- Sodium citrate
- Citric acid monohydrate
- Sodium hydroxide
- Hydrochloric acid
- Water for injections

Supplier

In Australia:

Juniper Biologics Pty Ltd
Level 14 Suite 3A16 275 Alfred Street
North Sydney
NSW 2060
Australia
AUSTRALIA

Australian Registration Number

ALOXI 250 microgram per 5 mL injection

AUST R 114185

ALOXI 75 microgram per 1.5 mL injection

AUST R 281464

This leaflet was modified May
2022.

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