

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ALOXI?

ALOXI contains the active ingredient palonosetron. ALOXI is used to prevent nausea and vomiting that happens with cancer chemotherapy, or up to 24 hours while recovering from anaesthesia after surgery.

For more information, see Section [1. Why am I using ALOXI?](#) in the full CMI.

2. What should I know before I use ALOXI?

Do not use if you have ever had an allergic reaction to palonosetron or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ALOXI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALOXI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ALOXI?

- ALOXI is administered by a doctor or nurse as an injection into a vein about 30 minutes before the start of chemotherapy or right before anaesthesia for surgery.

More instructions can be found in Section [4. How do I use ALOXI?](#) in the full CMI.

5. What should I know while using ALOXI?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ALOXI.• Tell your doctor if the medicine starts to upset you or your symptoms become worse• Tell your doctor if you become pregnant during treatment with ALOXI.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• Store ALOXI at 25°C in the original container to protect from light.

For more information, see Section [5. What should I know while using ALOXI?](#) in the full CMI.

6. Are there any side effects?

Common side effects of ALOXI are headache, dizziness, constipation and diarrhoea. Serious side effects include allergic reactions. Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you experience shortness of breath, wheezing or difficulty breathing, tightness of the chest, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALOXI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALOXI.**

Where to find information in this leaflet:

- [1. Why am I using ALOXI?](#)
- [2. What should I know before I use ALOXI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ALOXI?](#)
- [5. What should I know while using ALOXI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ALOXI?

ALOXI contains the active ingredient palonosetron. ALOXI is a serotonin (5-HT₃) antagonist.

ALOXI is used to prevent 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.

2. What should I know before I use ALOXI?

Warnings

Do not use ALOXI if:

- you are allergic to palonosetron, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any medicines, or any other substances such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with ALOXI and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALOXI.

4. How do I use ALOXI?

How much is given

- ALOXI is given as an injection into a vein by a doctor or nurse.
- Your doctor will decide how much of this medicine you will be given and for how long.

When to be given ALOXI

- ALOXI is given:
 - about 30 minutes before the start of chemotherapy or
 - right before anaesthesia for surgery.
- ALOXI is intended for single use in one patient.

If you are given too much ALOXI

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.

5. What should I know while using ALOXI?

Things you should do

Call your doctor straight away if:

- ALOXI starts to upset you or your symptoms become worse
- you become pregnant during treatment with this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ALOXI.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALOXI affects you.

It is not known if ALOXI 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C
- Store in the original container to protect from light.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Once opened your doctor or nurse will discard any unused portion of this medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General effects <ul style="list-style-type: none"> • headache • dizziness 	Speak to your doctor if you have any of

<ul style="list-style-type: none"> • weakness or tiredness • hiccups or dry mouth • fever or a flu-like illness • difficulty passing water 	these less serious side effects and they worry you.
Digestive system related <ul style="list-style-type: none"> • constipation • diarrhoea • upset stomach • stomach pain • flatulence (wind) • loss of appetite 	
Heart related <ul style="list-style-type: none"> • slower and faster heartbeat 	
Head related <ul style="list-style-type: none"> • anxiety or euphoria • sleep disturbances • visual or hearing disturbances • motion sickness 	
Body related <ul style="list-style-type: none"> • change of sensation in your limbs • joint pain • prominent or discoloured veins 	

Serious side effects

Serious side effects	What to do
Allergic reaction related <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing or a tight feeling in your chest • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALOXI contains

Active ingredient (main ingredient)	Palonosetron (as the hydrochloride)
Other ingredients (inactive ingredients)	Mannitol Disodium edetate Sodium citrate Citric acid monohydrate Sodium hydroxide Hydrochloric acid Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What ALOXI looks like

ALOXI solution for injection is a clear, essentially colourless solution in a clear glass vial.

ALOXI 250 microgram per 5 mL injection (AUST R 114185)

ALOXI 75 microgram per 1.5 mL injection (AUST R 281464)

Who distributes ALOXI

Juniper Biologics Pty Ltd

Level 14 Suite 3A16 275 Alfred Street

North Sydney

NSW 2060

Australia

Ph: 1800 281 493

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