

Package leaflet: Information for the patient

Aloxi 500 micrograms soft capsules Palonosetron

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aloxi is and what it is used for
2. What you need to know before you take Aloxi
3. How to take Aloxi
4. Possible side effects
5. How to store Aloxi
6. Contents of the pack and other information

1. What Aloxi is and what it is used for

Aloxi contains the active substance palonosetron. This belongs to a group of medicines called ‘serotonin (5HT₃) antagonists’.

Aloxi is used in adults to help stop you feeling or being sick (nausea and vomiting) when having cancer treatments called chemotherapy.

It works by blocking the action of a chemical called serotonin, which can cause you to feel sick or to vomit.

2. What you need to know before you take Aloxi

Do not take Aloxi if:

- you are allergic to palonosetron or any of the other ingredients of this medicine (listed in section 6).

Do not take Aloxi if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aloxi if:

- you have a blocked bowel or have had repeated constipation in the past
- you have had heart problems or heart problems run in your family, such as changes in your heart beat (‘QT prolongation’)
- you have an imbalance of certain minerals in your blood which has not been treated - such as potassium and magnesium.

Children

Do not give this medicine to children

Other medicines and Aloxi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking the following medicines:

Medicines for depression or anxiety

Tell your doctor or pharmacist if you are taking any medicines for depression or anxiety, including:

- medicines called SSRIs ('selective serotonin reuptake inhibitors') – such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- medicines called SNRIs ('serotonin noradrenaline reuptake inhibitors') – such as venlafaxine, duloxetine (can lead to the development of serotonin syndrome and should be used with caution).

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Aloxi.

Medicines that can affect your heart beat

Tell your doctor or pharmacist if you are taking any medicines that affect your heart beat – this is because they could cause heart beat problems when taken with Aloxi. This includes:

- medicines for heart problems such as amiodarone, nicardipine, quinidine
- medicines for infections such as moxifloxacin, erythromycin
- medicines for serious mental health problems such as haloperidol, chlorpromazine, quetiapine, thioridazine
- a medicine for feeling or being sick (nausea and vomiting) called domperidone.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Aloxi – this is because these medicines could cause heart beat problems when taken with Aloxi.

Pregnancy

If you are pregnant or think you might be pregnant, your doctor will not use Aloxi unless it is clearly necessary. This is because we do not know if Aloxi may harm the baby.

Ask your doctor or pharmacist for advice before using this medicine if you are pregnant or think you might be.

Breast-feeding

It is not known if Aloxi is found in breast milk.

Ask your doctor or pharmacist for advice before using this medicine if you are breast-feeding.

Driving and using machines

You may feel dizzy or tired after taking this medicine. If this happens, do not drive or use any tools or machines.

Aloxi contains sorbitol and may contain traces of soya

This medicine contains 7 mg sorbitol (a type of sugar) in each capsule. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Aloxi may contain traces of lecithin which comes from soya. If you are allergic to peanut or soya, do not take this medicine. See your doctor straight away if you notice any signs of an allergic reaction. The signs may include hives, skin rash, itching, difficulty breathing or swallowing, swollen mouth, face, lips, tongue or throat and sometimes a drop in blood pressure.

3. How to take Aloxi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one capsule (500 micrograms).
- You will normally take the capsule about 60 minutes before the start of your chemotherapy.
- This medicine can be taken with or without food.

It is not recommended to take Aloxi in the days following chemotherapy unless you are going to have another chemotherapy cycle.

If you take more Aloxi than you should

If you think you may have taken more than you should, tell your doctor straight away.

If you forget to take Aloxi

It is unlikely that you will forget to take this medicine. However, if you think you have forgotten to take your dose, tell your doctor straight away.

If you stop taking Aloxi

Do not stop taking this medicine without talking to your doctor. If you decide not to take Aloxi (or other similar medicines), it is likely your chemotherapy will cause you to feel sick or be sick (nausea and vomiting).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects:

- allergic reaction - the signs may include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing, an itchy, lumpy rash (hives). This is very rare: may affect up to 1 in 10,000 people.

Tell your doctor straight away if you notice any of the serious side effects listed above.

Other side effects

Tell your doctor if you notice any of the following side effects:

Common: may affect up to 1 in 10 people

- headache.

Uncommon: may affect up to 1 in 100 people

- trouble sleeping
- shortness of breath
- eye swelling
- abnormal electrical impulses in the heart
- constipation
- feeling sick (nausea)
- high levels of the pigment 'bilirubin' (a marker of liver problems) in the blood

- muscle pain.

Tell your doctor if you notice any of the side effects listed above.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aloxi

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Aloxi contains

- The active substance is palonosetron. Each capsule contains 500 micrograms palonosetron (as hydrochloride).
- The other ingredients are glycerol monocaprylocaproate (type I), polyglycerol oleate, glycerol, purified water, butylhydroxyanisole, gelatin, sorbitol, titanium dioxide.

What Aloxi looks like and contents of the pack

Aloxi 500 micrograms soft capsules are plain, light beige, opaque, round to oval soft capsules, filled with a clear yellowish solution. They are supplied in polyamide/aluminium/PVC blisters containing one or five capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>