

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrAkynzeo™ (netupitant / palonosetron capsules)

Read this carefully before you start taking **Akynzeo** 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 **Akynzeo**.

Serious Warnings and Precautions

Akynzeo can interact with certain medications that are broken down by similar liver enzymes. Tell your doctor which medications you are taking.

What is Akynzeo used for?

Prevention of nausea (feeling sick) and vomiting that may happen after taking certain anti-cancer medicines (chemotherapy). You will take **Akynzeo** with another medication called dexamethasone.

Akynzeo can help prevent nausea and vomiting during two different phases:

- Acute phase: within 24 hours of chemotherapy
- Delayed phase: ongoing nausea and vomiting for 5 days after chemotherapy

How does Akynzeo work?

Akynzeo is a type of medication called an “anti-emetic.” It contains a combination of palonosetron and netupitant:

- palonosetron prevents nausea and vomiting during the acute phase
- netupitant prevents nausea and vomiting during the delayed phase after cancer chemotherapy.

What are the ingredients in Akynzeo?

Medicinal ingredients: netupitant and palonosetron (as palonosetron hydrochloride).

Non-medicinal ingredients: glycerol monocaprylocaprate, microcrystalline cellulose, sucrose lauric acid esters, povidone K-30, croscarmellose sodium, colloidal hydrated silica, sodium stearyl fumarate, magnesium stearate, glycerin, polyglyceryl dioleate, purified water, butylated hydroxyanisole (BHA), gelatin, sorbitol, 1,4 sorbitan, titanium dioxide, shellac glaze (partially esterified), yellow, red and black iron oxide, propylene glycol. May contain traces of lecithin derived from soya, medium-chain triglycerides, and denatured ethanol.

Akynzeo comes in the following dosage form:

Capsule: 300 mg netupitant / 0.5 mg palonosetron (as palonosetron hydrochloride)

Do not use Akynzeo if:

- you are allergic to netupitant or palonosetron or any of the other ingredients in **Akynzeo**;
- you are pregnant or planning to become pregnant during therapy and up to one month after treatment with **Akynzeo**;
- you take pimozide, terfenadine, astemizole, or cisapride. Taking **Akynzeo** with these medications could result in serious or life-threatening problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Akynzeo. Talk about any health conditions or problems you may have, including if 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;
- have low levels of potassium or magnesium;
- have high blood pressure;
- have liver or kidney problems;
- have acute bowel blockage or a history of repeated constipation;
- are allergic to other 5-HT₃ receptor antagonists such as ondansetron, dolasetron, or granisetron;
- are allergic to sorbitol or sucrose. If you do, you should not take **Akynzeo**.

Other warnings you should know about:

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

Do not take **Akynzeo** if you are less than 18 years old.

Driving and using machines:

Akynzeo may influence your ability to drive and use machines. Do not drive or use machines until you know how you feel while taking **Akynzeo**. It may cause dizziness, drowsiness or may make you feel tired.

Soya Allergy:

Akynzeo may contain a trace of lecithin derived from soya. If you have a peanut or soya allergy you may be monitored for signs of an allergic reaction.

Pregnancy:

Do not take **Akynzeo** if you are pregnant or are planning to get pregnant. Your doctor may ask you to take a pregnancy test before you start treatment with **Akynzeo**. You must use effective birth control (such as ‘the pill’) during treatment with **Akynzeo** and up to one month after treatment.

Nursing Women:

Do not use **Akynzeo** if you are breast-feeding and for 1 month after your last dose.

Serotonin Syndrome:

Serotonin Syndrome is a rare but potentially life-threatening reaction that can occur with “antiemetic” medicines. 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. Be sure to tell your healthcare professional all the medicines you are taking.

The following may interact with Akynzeo:

- pimozide (an antipsychotic)
- terfenadine, astemizole (allergy medications)
- cisapride (used to treat reflux)
- chemotherapeutic agents such as docetaxel, etoposide, cyclophosphamide
- serotonergic drugs (including SSRIs, SNRIs) used to treat depression and/or anxiety disorders. These may increase the risk of Serotonin Syndrome.
- digoxin (used to treat certain heart conditions)
- zidovudine, ritonavir (used to treat HIV/AIDS)
- rifampin (antibiotics)
- ketoconazole (an antifungal)
- valproic acid (used to treat epilepsy)
- morphine (for pain)
- drugs that may lengthen the QT-interval of your heart (examples include certain drugs to treat heart conditions, psychosis, depression, pain, infections and other conditions)
- drugs that may affect the levels of electrolytes in your body (examples include certain diuretics, laxatives, enemas and corticosteroids)
- grapefruit and grapefruit juice

How to take Akynzeo:

- Take one **Akynzeo** capsule about 1 hour before the start of your chemotherapy cycle.
- Do not use **Akynzeo** to treat nausea or vomiting in the days after your chemotherapy. Only take it when you are one hour from a chemotherapy cycle, or as prescribed by your doctor.
- You will be given a specific amount of dexamethasone to take at specific times. This will depend on the type of chemotherapy you are taking.
- **Akynzeo** should be swallowed whole. It can be taken with or without food.
- Do not change your dose without consulting your doctor.

Refilling your Prescription for Akynzeo:

A prescription is required from your doctor each time you need more **Akynzeo**. It is important that you contact your doctor before your current supply runs out.

Overdose:

If you think you have taken too much **Akynzeo**, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you think you have forgotten to take your dose, tell your doctor straight away.

What are possible side effects from using Akynzeo?

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

Common side effects may include:

- headache
- constipation
- fatigue (feeling tired)

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	
VERY RARE Severe allergic reaction (anaphylaxis): hives, skin rash, itching, difficulty breathing or swallowing, swollen mouth, face, lips, tongue or throat and sometimes a drop in blood pressure			√
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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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 15-30°C.
- Keep out of the reach and sight of children.

If you want more information about Akynzeo:

- 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) (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.elvium.ca>, or by calling 1-833-744-0005.

This leaflet was prepared by Elvium Life Sciences.

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