

AKYNZEO

Before Chemo



Focus on You,
Not on Nausea and Vomiting

*I feel more like
myself*



Your guide to AKYNZEO and chemo-related nausea and vomiting

What is AKYNZEO?

AKYNZEO (netupitant and palonosetron) capsules/(fosnetupitant and palonosetron) for injection is a prescription medicine called an “antiemetic.” AKYNZEO is used in combination with the medicine dexamethasone in adults to help prevent the nausea and vomiting that happens right away or later with certain anti-cancer medicines (chemotherapy).

It is not known if AKYNZEO is safe and effective in children under 18 years of age.

Only take AKYNZEO as prescribed by your doctor. For additional information about AKYNZEO, talk to your doctor.

Please see the Summary of Important Information about AKYNZEO on the next page.

The information in this brochure is intended for educational purposes only and is not a substitute for medical advice.

 Akynzeo®

netupitant 300 mg/
palonosetron 0.5 mg
capsule

fosnetupitant 235 mg/
palonosetron 0.25 mg
for injection

Important Safety Considerations

- **AKYNZEO may cause serious allergic reactions**, such as anaphylaxis. **Get emergency medical help right away** if you get any of the following symptoms of a serious allergic reaction: hives, swollen face, trouble breathing, or chest pain
- **Serotonin syndrome** can happen with AKYNZEO particularly with certain other medicines such as anti-depressants and anti-migraine medicines and can be life-threatening. **Stop taking AKYNZEO capsules and go to the nearest hospital emergency room right away if you get any of the following symptoms:** agitation, hallucinations or other changes in mental status, dizziness, fast heartbeat, sweating, low body temperature, shaking (tremors), unsteady movements, muscle twitching (overactive reflexes), or seizures with or without nausea, vomiting, and diarrhea
- The most common side effects of AKYNZEO capsules and injection include: headache, weakness, fatigue, upset stomach, constipation, and skin redness
- Tell your doctor or nurse about all your medical conditions including if you are taking other medications or if you are pregnant or breastfeeding or plan to become pregnant or breastfeed

Only take AKYNZEO as prescribed by your doctor. For additional information about AKYNZEO, talk to your doctor or see the full Prescribing Information at www.akynzeo.com

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Summary of Important Information about Akynzeo

What is AKYNZEO?

AKYNZEO (netupitant and palonosetron) capsules/ (fosnetupitant and palonosetron) for injection is a prescription medicine called an “antiemetic.” AKYNZEO is used in combination with the medicine dexamethasone in adults to help prevent the nausea and vomiting that happens right away or later with certain anti-cancer medicines (chemotherapy).

It is not known if AKYNZEO is safe and effective in children under 18 years of age.

What should I tell my doctor before taking AKYNZEO?

Before taking AKYNZEO, tell your doctor about all your medical conditions, including if you:

- have had an allergic reaction to palonosetron or another medication for nausea or vomiting.
- have liver or kidney problems
- are pregnant or plan to become pregnant. It is not known if AKYNZEO will harm your unborn baby.

- are breastfeeding or plan to breastfeed. It is not known if AKYNZEO passes into your breast milk. You and your doctor should decide if you will take AKYNZEO or breastfeed. You should not do both.

What other medications might interact with AKYNZEO?

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements as they might interact with AKYNZEO.

- AKYNZEO can affect certain medications that are metabolized through the liver.
- In addition, certain medications, when taken with AKYNZEO may lead to a serious side effect known as serotonin syndrome. Serotonin syndrome can be fatal.

What are the possible side effects of AKYNZEO?

AKYNZEO may cause serious side effects, including:

- **Allergic Reactions**, such as anaphylaxis. Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction with AKYNZEO: hives, swollen face, trouble breathing, or chest pain.
- **Serotonin syndrome** which can happen with AKYNZEO particularly with certain other medicines such as antidepressants and anti-

migraine medicines and can lead to death. **Go to the nearest hospital emergency room right away if you get any of the following symptoms:** agitation, hallucinations or other changes in mental status, dizziness, muscle twitching (overactive reflexes), or seizures.

The most common side effects of AKYNZEO are headache, weakness, fatigue, upset stomach, constipation, and skin redness.

These are not all the possible side effects of AKYNZEO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

The risk information provided here is not comprehensive. For additional information on AKYNZEO:

- **Talk to your healthcare provider or pharmacist**
- **Visit www.AkynzeoPI.com** (https://www.akynzeo.com/assets/pdf/Prescribing_Information.pdf) **to obtain the FDA approved full Prescribing Information**
- Contact Helsinn Medical Information at 1-84HELSINN-U (1-844-357-4668; option 1)



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Going through chemo for the first time, or again, is tough.

It may be more difficult if you have side effects such as nausea and vomiting.

This brochure was designed as a guide to help you and your loved ones learn more about chemo-related nausea and vomiting.

It will also introduce you to AKYNZEO (a kin zee oh), a prescription medicine used to help prevent the nausea and vomiting that happens right away or later with certain chemo medicines.

What Is It?

Chemotherapy-related nausea and vomiting are side effects of chemotherapy medicines, or **chemo**, for short. Side effects happen when chemo damages healthy cells. You may also hear or see the term **chemotherapy-induced nausea and vomiting**, or **CINV**.

- **Nausea** is the feeling you have when you need to vomit, or throw up
- **Vomiting** is the act of throwing up what is in your stomach

Some people may or may not have these side effects. Some people may have nausea or vomiting, or both.

For some people, nausea can be worse than vomiting, because once it starts it can be hard to stop. **The goal is prevention.**

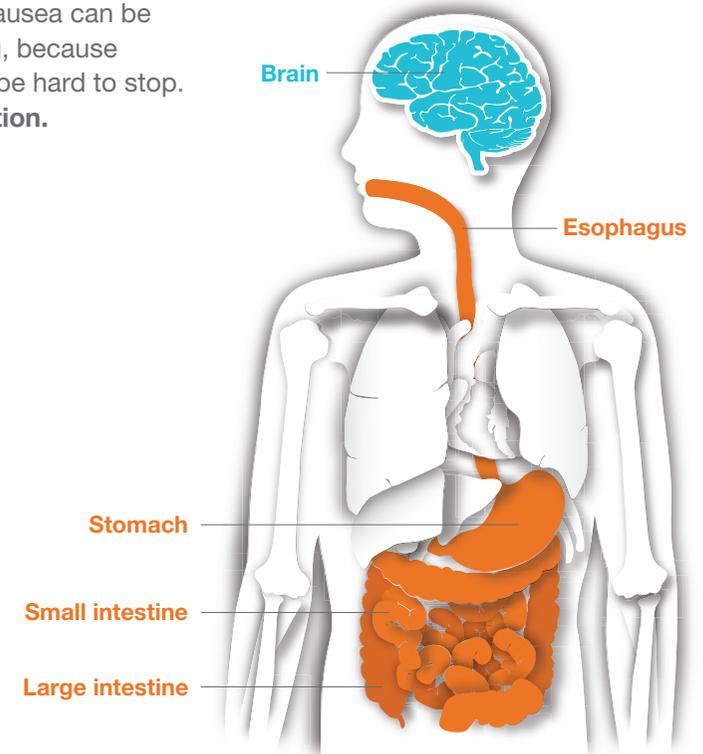
How Does It Happen?

When you receive chemo, **two things may happen in your body:**

- A certain part of your **brain** is triggered
- Certain areas of your **esophagus, stomach, and small and large intestine** are triggered

These triggers start a process that leads to nausea and vomiting.

Medicines can be used to block this process to help prevent nausea and vomiting.



When Can It Affect Me?

Chemo-related nausea and vomiting can happen soon after treatment with chemo or as long as several days later.

- **Acute chemo-related nausea and vomiting** usually occurs within the first 24 hours after you receive chemo treatment
- **Delayed chemo-related nausea and vomiting** occurs 24 hours or more after you receive chemo treatment

Am I at Risk?

The risk factors for chemo-related nausea and vomiting are different for everyone.

Some people are more likely than others to have nausea and vomiting. Nausea and vomiting caused by chemo can happen for different reasons. Some of those reasons may include your individual risk factors, such as your age or medical history.

Your chemo medicines may be more likely to cause these effects, and different types of chemo are more likely than others to do this.

Here are some of the individual risk factors that may increase your risk of chemo-related nausea and vomiting:



Your type of chemo regimen



You have a history of motion sickness



You are a woman



You suffered nausea and vomiting during past chemo treatments



You had episodes of vomiting during pregnancy



You don't drink alcohol or drink it only occasionally



You are younger than 50 years old

If any of these apply to you, it may be even more important to get treatment to prevent chemo-related nausea and vomiting.



Speak with your doctor about your options for stopping chemo-related nausea and vomiting **before it starts.**

Not an actual patient.
Individual results may vary.

What Types of Chemo Medicines Cause It?

Some chemo medicines are more likely than others to cause nausea and vomiting. Chemo medicines are grouped according to how likely they are to cause nausea and vomiting.

- The ones most likely to cause nausea and vomiting are called **highly emetogenic** (eh-MET-oh-JEN-ic)
- Other chemo medicines that are less likely to cause these effects are considered **moderately emetogenic**

Emesis is a medical term for vomiting. **Emetogenic** refers to a medicine that causes nausea and vomiting.

When some chemo medicines are given in high doses, or when they are given together, they can make the nausea and vomiting worse.

Without any preventive treatments, moderately emetogenic medicines cause nausea and vomiting in

**30% TO 90%
OF PATIENTS.**

Without any preventive treatments, highly emetogenic medicines cause nausea and vomiting in

**MORE THAN 90%
OF PATIENTS.**

Ways to Prevent It

Medicines used to help prevent nausea and vomiting are called **antiemetics**. There are different classes, or groups, of antiemetics. **They are grouped according to how they work in the body.**

- Some block triggers and signals from your brain
- Others block triggers and signals from your stomach, saliva gland, and intestines

Doctors may prescribe medicines to help prevent nausea and vomiting that work in other ways.

Antiemetics are taken in different ways:



You can take antiemetics by mouth in the form of a pill or capsule, either swallowed or dissolved under your tongue



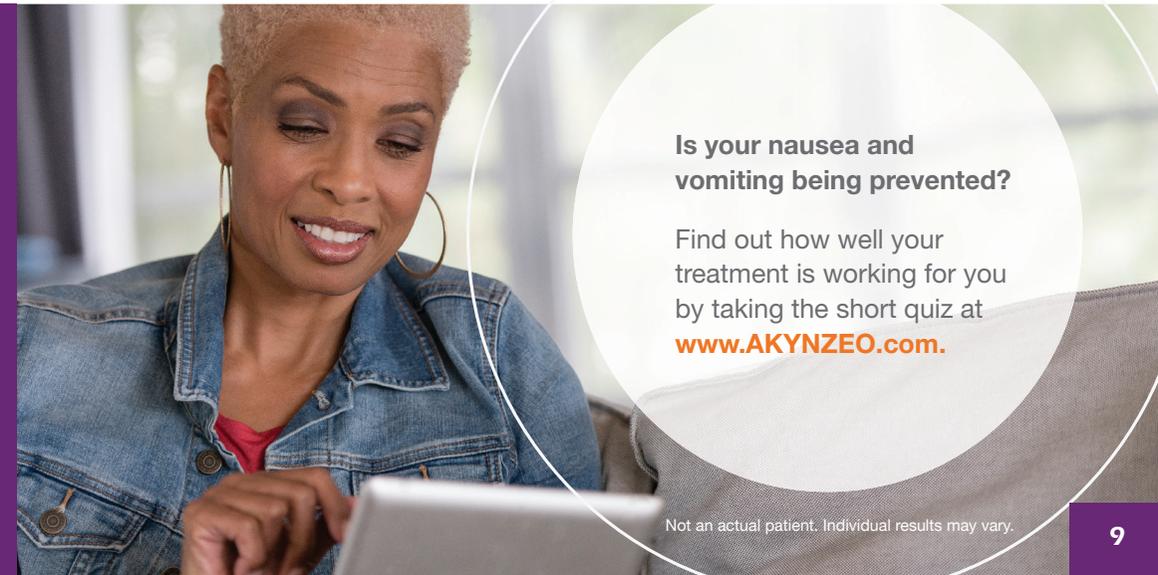
They may also be given by a doctor through an injection or an intravenous (IV) line



Your doctor will tell you when to take your antiemetic before your chemo treatment



Ask your doctor if the chemotherapy prescribed for you is likely to cause nausea and vomiting.



Is your nausea and vomiting being prevented?

Find out how well your treatment is working for you by taking the short quiz at www.AKYNZEO.com.

Not an actual patient. Individual results may vary.

Working With Your Doctor

It is important to talk to your doctor about your risk of chemo-related nausea and vomiting so that he or she can help you prevent it. Here are some tips to help you speak with your doctor.



Be descriptive. It can be hard for you to describe how much nausea affects you, so try to be as detailed and descriptive as possible when you talk to your doctor about it. Make sure to tell your doctor any other symptoms that you have when you have nausea.



Keep a journal. Try to keep track of the side effects and of how you are feeling during treatment. You may wish to use a journal to help keep your information in one place. This journal can help your doctor understand how often or how badly nausea and vomiting has affected you.



Ask questions. You should find out about the possible side effects of the chemo you will be receiving. Ask your doctor if the therapy prescribed for you is likely to cause nausea and vomiting.



Not an actual patient.
Individual results may vary.

Need help getting the conversation started? Download the patient discussion guide at www.AKYNZEO.com.

How AKYNZEO Works

AKYNZEO is a prescription medicine that is used in people to help prevent the nausea and vomiting that happens right away (acute) or later (delayed) with certain chemo medicines.

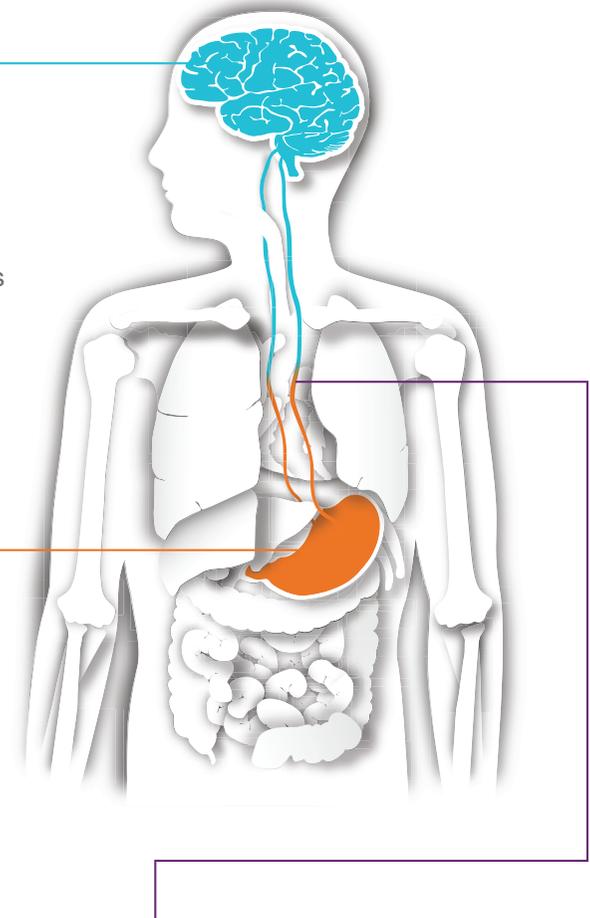
AKYNZEO is a combination medicine. It contains two medicines: **PALONOSETRON** and **NETUPITANT or FOSNETUPITANT**. These medicines are from two different classes. Two different classes means AKYNZEO works on two different pathways in your body to prevent nausea and vomiting.

NETUPITANT

is thought to work by blocking signals from your **brain** to protect against nausea and vomiting. It helps relieve the nausea and vomiting that happens right away or later (acute or delayed). Fosnetupitant is converted to netupitant within the body.

PALONOSETRON

is thought to work by blocking signals from the **stomach** to protect against nausea and vomiting that happens right away (acute).



AKYNZEO is the first and only combination medicine that blocks both of these pathways.

Proven Protection

AKYNZEO works to prevent nausea and vomiting from highly and moderately emetogenic chemo medicines, including some medicines that are used in the treatment of breast and lung cancer.

AKYNZEO has also prevented nausea and vomiting for people who have had several cycles of chemo.

In a clinical study for the AKYNZEO pill, the most common side effects of stomach upset, fatigue, constipation, and skin redness occurred in 4% of patients or fewer. In another clinical study, the safety of AKYNZEO injection was found to be similar to that of the AKYNZEO pill.

In a clinical study involving **135 patients** who were taking cisplatin-based chemotherapy, patients given an oral dose of AKYNZEO with dexamethasone were compared against patients given an oral dose of palonosetron, a different antiemetic treatment, with dexamethasone:



90%

of patients who received AKYNZEO had **no vomiting for as long as 5 days** after chemo.



99%

of patients who received AKYNZEO had **no vomiting within 24 hours** of chemo.

5
days

In clinical studies, a single dose of oral AKYNZEO with dexamethasone prevented vomiting for as long as 5 days after chemo.

When to Take AKYNZEO

AKYNZEO is given by your doctor as a pill by mouth or as an intravenous injection before your treatment at the start of each chemo cycle.

- AKYNZEO is given with dexamethasone
- AKYNZEO can be taken with or without food

If you are prescribed AKYNZEO for injection, it will be given to you about **30 minutes** before your chemo treatment.



If you are prescribed the AKYNZEO pill, you take it about **1 hour** before your chemo treatment.

- If you are going to an infusion center for your chemo treatment, you may need to bring your AKYNZEO pill with you
- Your doctor will tell you exactly when to take your AKYNZEO pill
- If you take too much AKYNZEO, call your doctor or go to the nearest emergency room right away

Need help opening the AKYNZEO pack?

Download the Instructions for Use card at www.AKYNZEO.com.

Actor portrayal.
Individual results may vary.



Dosing Recommendations

Dexamethasone is a steroid that is used to treat inflammation, or swelling, in the body and is usually given with most antiemetics, including AKYNZEO.

- When given with AKYNZEO, dexamethasone is usually taken by mouth
- For patients receiving a **highly emetogenic** chemo medicine, the doctor may also prescribe dexamethasone **for 3 days after** receiving chemo treatment

Type of chemo medicine	Day of chemo (day 1)	After chemo (days 2-4)
Highly emetogenic	AKYNZEO pill and dexamethasone 12 mg	Dexamethasone 8 mg once a day
	<i>or</i>	
	AKYNZEO injection and dexamethasone 12 mg	Dexamethasone 8 mg once a day
Moderately emetogenic	AKYNZEO pill and dexamethasone 12 mg	

Before taking AKYNZEO, tell your doctor about all of your medical conditions, including if you

- have had an allergic reaction to palonosetron or another medication for nausea or vomiting
- have liver or kidney problems
- are pregnant or plan to become pregnant. It is not known if AKYNZEO will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if AKYNZEO passes into your breast milk. You and your doctor should decide if you will take AKYNZEO or breastfeed. You should not do both

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, as they might interact with AKYNZEO.

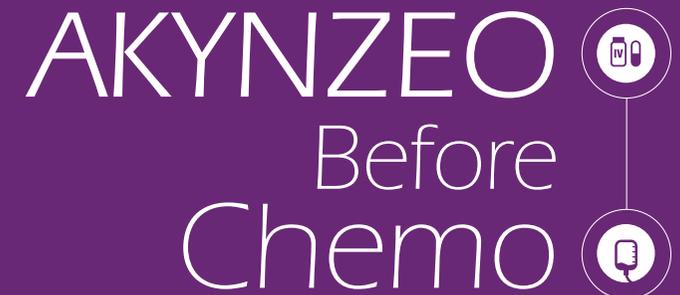
- AKYNZEO can effect certain medications that are metabolized through the liver
- In addition, certain medications, when taken with AKYNZEO may lead to a serious side effect known as serotonin syndrome. Serotonin syndrome can be fatal

Helsinn Cares Patient Support Program

You should **focus on your fight with cancer**, not nausea and vomiting. If you are concerned about paying for AKYNZEO, you may be eligible to take part in the Helsinn Cares Patient Support Program.



Visit HelsinnCares.com to find out more about AKYNZEO patient access programs.



*Restrictions apply. May not be available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, Medigap, VA, DoD, or TRICARE.

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Learn more

Visit the AKYNZEO website at www.AKYNZEO.com for more information, tools, and resources about AKYNZEO and chemo-related nausea and vomiting.

The American Cancer Society

www.cancer.org

CancerCare

www.cancer.org

National Cancer Institute

www.cancer.gov

Cancer Support Community

www.cancersupportcommunity.org

National Comprehensive Cancer Network

www.nccn.org/patients

www.akynzeo.com

Please see the Important Safety Considerations for AKYNZEO on pages 2-3.

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 **HELINN**

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