

Helsinn Group announces AKYNZEO® (fosnetupitant/palonosetron) injection is now available in a ready-to-use vial in the US

Lugano, Switzerland – June 24, 2024 – Helsinn Group (“Helsinn”), a global pharmaceutical company with a track record of over forty-five years of commercial execution and a strong focus in supportive care, oncology and dermato-oncology, is pleased to announce that AKYNZEO® (fosnetupitant/palonosetron) injection is now available in the US in a ready-to-use vial.

AKYNZEO injection (Ready-to-Use) is a new method of administration and contains the same formulation as the prior AKYNZEO Injection (To-be-Diluted).

The features of the new ready-to-use presentation of AKYNZEO injection include:

- No reconstitution or dilution required; infuse directly from the vial using a built-in hanging strap
- No refrigeration required at any point during distribution, storage, or preparation
- Accessible via automated dispensing machine, allowing the product to be stored and available near the location of patient care

AKYNZEO injection is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. It has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy. AKYNZEO injection does not contain polysorbate 80 or allergenic excipients such as soy or egg lecithin. It can be administered simultaneously with intravenous dexamethasone sodium phosphate.

Dr. Melanie Rolli, Helsinn Group CEO, commented: “As a pioneer in cancer supportive care, Helsinn continues to be unwavering in our pursuit to help patients and clinicians in cancer care. We are very pleased to launch the new AKYNZEO Ready-to-Use vial, building on our legacy of innovation.”

Ordering information



Clinicians wishing to order the new vial should contact their GPO or distributor. The National Drug Code (NDC) number for AKYNZEO injection vial with hanger (Ready-to-Use) is 69639-106-01 and the J Code is J1454 (Injection, fosnetupitant 235 mg and palonosetron 0.25 mg); billing unit (single dose vial [SDV]).

About AKYNZEO®

AKYNZEO is the first and only 5-HT₃ and NK₁ receptor antagonists fixed combination approved for the prevention of chemotherapy-induced acute and delayed nausea and vomiting. A single dose of AKYNZEO given with dexamethasone has been shown to prevent chemotherapy-induced nausea and vomiting for up to 5 days.

INDICATION

AKYNZEO (fosnetupitant/palonosetron) injection is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

Limitations of Use

AKYNZEO injection has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

AKYNZEO is a combination of palonosetron, a serotonin-3 (5-HT₃) receptor antagonist, and fosnetupitant, a substance P/neurokinin-1 (NK-1) receptor antagonist: palonosetron prevents nausea and vomiting during the acute phase and fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron, one of the components of AKYNZEO, with or without known hypersensitivity to other 5-HT₃ receptor antagonists.
- Serotonin syndrome has been reported with 5-HT₃ receptor antagonists alone but

particularly with concomitant use of serotonergic drugs. Serotonin syndrome can be life threatening. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes, autonomic instability, neuromuscular symptoms, seizures, and gastrointestinal symptoms. Patients should be monitored for the emergence of serotonin syndrome, and if symptoms occur, discontinue AKYNZEO and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if AKYNZEO is used concomitantly with other serotonergic drugs.

Adverse Reactions

Most common adverse reactions ($\geq 3\%$) for AKYNZEO capsules are headache, asthenia, dyspepsia, fatigue, constipation and erythema. The safety profile of AKYNZEO injection was generally similar to AKYNZEO capsules.

Drug Interactions

- Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4. The plasma concentrations of CYP3A4 substrates can increase when co-administered with AKYNZEO. The inhibitory effect on CYP3A4 can last for multiple days
 - Dexamethasone doses should be reduced when given with AKYNZEO. A more than two- fold increase in the systemic exposure of dexamethasone was observed 4 days after a single infusion of fosnetupitant.
 - Consider the potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) when administering with AKYNZEO. When administered with netupitant, the systemic exposure to midazolam was significantly increased.
- Avoid concomitant use of AKYNZEO in patients on chronic use of a strong CYP3A4 inducer such as rifampin as this may decrease the efficacy of AKYNZEO.

Use in Specific Populations

- Avoid use of AKYNZEO in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease.
- Advise women of potential risk to fetus; limited data are available; may cause fetal harm.



For more information about AKYNZEO® please see the full [US Prescribing Information](#).

About Helsinn

Helsinn is a global pharmaceutical company that builds, manufactures, launches, and commercializes products to improve the quality of life for patients with cancer and chronic disease, with a focus on supportive care, oncology and dermato-oncology. Helsinn, headquartered in Lugano, Switzerland, has direct commercial operations in the U.S. and an extensive network of long-standing trusted partners enabling a commercial presence in more than 90 countries.

Established in 1976, Helsinn is a third-generation family-owned company with broad pharmaceutical and technical expertise. Helsinn is proud of its history of operating with great integrity, passion and quality. The company is committed to continuously striving for innovation for its patients and embracing sustainable growth as a core element of its strategic vision.

To learn more about Helsinn, please visit www.helsinn.com or follow us on [LinkedIn](#) and [X](#).

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