

Helsinn Group Announces new Permanent J Code for AKYNZEO® (fosnetupitant and palonosetron) for injection in the US

- Akynzeo® for injection received a permanent J code, **J1454**, in the US, by the Centers for Medicare and Medicaid Services

Lugano, Switzerland, December 12th, 2018 – Helsinn, a Swiss pharmaceutical group, today announces that Akynzeo® for injection has been assigned the new permanent J code, J1454, in the US by the Centers for Medicare and Medicaid Services (CMS), effective January 1, 2019.

The new permanent and unique J code for Akynzeo® for injection will be used by all payers in the US for reimbursement, including Medicare, Medicaid and all other commercial payers. The J code will help time to payment and claims processing challenges for providers.

“Receiving a unique and permanent J code for Akynzeo® for injection will significantly streamline and simplify the reimbursement process for practices and as a result more patients will gain access to Akynzeo®.” said Paul Rittman, Chief Executive Officer of Helsinn Therapeutics, the US Subsidiary of Helsinn Group.

“This is a significant milestone for Helsinn as we continue our efforts in helping more patients with chemotherapy induced nausea and vomiting” added Riccardo Braglia, Helsinn Group Vice Chairman and CEO, “Helsinn’s goal is to help more patients with their cancer care, and we believe this is a significant step towards this”.

Akynzeo® is the first and only 5-HT₃ and NK₁ receptor antagonists combination agent approved for the prevention of chemotherapy induced acute and delayed nausea and vomiting. It is available only by prescription and is used in combination with dexamethasone in adults to help prevent the nausea and vomiting that happens right away or later with certain chemotherapy medicines. A single dose of Akynzeo for injection has been shown to prevent chemotherapy induced nausea and vomiting for 5 days. All billing and coding information, as well as other patient access resources, are available through the Helsinn Cares program.

To access Helsinn Cares or enroll a patient in the United States, please call 1-844-HELINN-U (1-844-357-4668) or visit <http://helsinnreimbursement.com>

About Akynzeo[®]

AKYNZEO (fosnetupitant 235mg and palonosetron 0.25mg) for 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. AKYNZEO for injection is a combination of palonosetron and fosnetupitant, a prodrug of netupitant: palonosetron prevents nausea and vomiting during the acute and delayed phase after cancer chemotherapy.

Limitations of Use

AKYNZEO for injection has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide 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 for AKYNZEO: headache, asthenia, dyspepsia, fatigue, constipation and erythema

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
- Avoid use in pregnancy, limited data is available, may cause fetal harm

For more information about AKYNZEO please see the [full Prescribing Information](#) or visit www.AKYNZEO.com

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco, and China, as well as a product presence in approximately 190 countries globally.

To learn more about Helsinn Group please visit www.helsinn.com

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For more information, please visit www.helsinn.com and follow us on [Twitter](#), [LinkedIn](#) and [Vimeo](#).

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