

AKYNZEO® (netupitant/palonosetron hydrochloride)**Prescribing Information for Akynzeo**

For full information please refer to the Summary of Product Characteristics before prescribing.

Presentations: 300 mg netupitant and palonosetron hydrochloride equivalent to 0.5 mg of palonosetron.

Indications: In adults, for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Dosage and Administration: Adults: One 300 mg/0.5 mg capsule administered approximately one hour prior to the start of each chemotherapy cycle. The hard capsule should be swallowed as a whole. The recommended oral dexamethasone dose should be reduced by approximately 50% when co-administered with Akynzeo capsules. Elderly: No dosage adjustment is necessary in the elderly. Caution should be exercised when using this product in patients over 75 years, due to the long half-life of the active substances and the limited experience in this population. Paediatric population: The safety and efficacy in children have not been established. Renal impairment: Dosage adjustment is not considered necessary in patients with mild to severe renal impairment. No data is available for patients with end stage renal disease requiring haemodialysis and therefore use in these patients should be avoided. Hepatic impairment: No dosage adjustment is necessary for patients with mild or moderate hepatic impairment. Limited data is available in severe hepatic impairment and therefore, should be used with caution in these patients.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Pregnancy.

Precautions and Warnings for Use: Palonosetron in Akynzeo may increase large bowel transit time and patients with a history of constipation or signs of subacute intestinal obstruction should be monitored following administration. There have been reports of serotonin syndrome with the use of 5-HT₃ antagonists either alone or in combination with other serotonergic medical products. Appropriate observation of patients for serotonin syndrome-like symptoms is advised. Caution should be exercised with the concomitant use of Akynzeo capsules and drugs that increase the QT interval or in patients who are likely to develop prolongation of the QT interval. Hypokalaemia and hypomagnesaemia should be corrected prior to administration. This medicinal product should be used with caution in patients receiving concomitant orally administered active substances that are metabolised primarily through CYP3A4 and with a narrow therapeutic range. Patients should be monitored for increased toxicity of chemotherapeutic agents that are substrates for CYP3A4. Netupitant in Akynzeo may also affect the efficacy of chemotherapeutic agents that need

activation by CYP3A4 metabolism. Contains sorbitol and sucrose. Patients with fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May also contain lecithin derived from soya. Patients with known hypersensitivity to peanut or soya, should be monitored closely for signs of an allergic reaction. Since Akynzeo capsules may cause dizziness, somnolence and fatigue, patients should be cautioned against driving and operating machinery if such symptoms occur.

Common Side Effects: Headache, constipation, fatigue.

Prescribers should consult the Summary of Product Characteristics in relation to other adverse reactions.

Legal Category: POM.

Package Quantities and Prices:

GB (PLGB 12333/0018): 1 x 300 mg/0.5 mg hard capsule £69

Northern Ireland (EU/1/15/1001/001): 1 x 300 mg/0.5 mg hard capsule £69

Ireland (EU/1/15/1001/001): 1 x 300 mg/0.5 mg hard capsule

Marketing Authorisation Holder: Helsinn Birex Pharmaceuticals Ltd., Damastown, Mulhuddart, Dublin 15, Republic of Ireland.

UK & Ireland Distributor: Chugai Pharma UK Limited, Ground Floor, Building 4, Chiswick Park, 566 Chiswick High Rd, Chiswick, London W4 5YE

Date of Preparation: January 2026.

C-GB-00002040

Additional Information is available in the SmPC or on request from Chugai Pharma UK Limited, Ground Floor, Building 4, Chiswick Park, 566 Chiswick High Rd, Chiswick, London W4 5YE.

Tel: +44 (0) 01748 827 276 Email: medinfo@chugai-pharm.co.uk

UK: Adverse events should be reported. Reporting forms and information can be found at

www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Chugai Pharma UK Ltd at pv@chugai-pharm.co.uk or Tel: +44 (0) 208 987 5600

Ireland: Adverse events should be reported. Reporting forms and information can be found at

www.hpra.ie. Adverse events should also be reported to Chugai Pharma UK Ltd. at pv@chugai-pharm.co.uk or Tel: +44 (0) 208 987 5600