

AKYNZEO® (netupitant/palonosetron)

300mg/0.5mg Hard Capsules

300 mg netupitant / 0.5 mg palonosetron

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What **AKYNZEO**® is used for

This medicine is a prescription medicine called an “antiemetic”. It is used in people 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.

How **AKYNZEO**® works

AKYNZEO® is combination medicine which contains two active ingredients called netupitant and palonosetron. Netupitant belongs to a group of medicines called ‘NK1 receptor antagonists’ and palonosetron belongs to a group of medicines called ‘serotonin (5HT3) antagonists’.

AKYNZEO® is used to prevent nausea and vomiting caused by chemotherapy (cancer treatment) in adult patients.

Before you use **AKYNZEO**®

When you must not use it

- If you are allergic (hypersensitive) to palonosetron or netupitant.
- If you are pregnant.

Before you start use it

Tell your doctor or pharmacist if you:

- have had an allergic reaction to palonosetron or another medicine for nausea or vomiting;
- have liver 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**® pass into your breast milk. You and your doctor should decide if you will take **AKYNZEO**® or breastfeed. You should not do both.

Always inform your doctor about all of the medicines you take, including prescription and over-the-counter, medicines, vitamins, and herbal supplements.

Seek medical advice from your doctor or pharmacist.

Children and adolescents

AKYNZEO® is not recommended for use in children and adolescents under 18 years.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

AKYNZEO® can affect other medicines both during and after treatment with **AKYNZEO**®.

The following medicines may require a dosage adjustment when taken with **AKYNZEO**®:

- Chemotherapy medicines such as docetaxel, paclitaxel, etoposide, irinotecan, or cyclophosphamide, ifosfamide, imatinib, vinorelbine, vinblastine, and vincristine.
- Midazolam (used as a sedative and to relieve anxiety), Dexamethasone (a steroid).

How to use **AKYNZEO**®

Route of administration: Oral

Take **AKYNZEO**® exactly as your doctor tells you to take it.

Take 1 **AKYNZEO**® capsule by mouth, about 1 hour before you get your anti-cancer medicine (chemotherapy).

Take **AKYNZEO**® with or without food.

For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.

When to use it

Use as directed by your doctor or pharmacist.

If you forget to use it

It is unlikely that you will forget to take **AKYNZEO**®, however, if you think you have forgotten to take your dose, inform your doctor immediately.

If you use too much (overdose)

If you take too much **AKYNZEO**®, call your doctor or go to the nearest emergency room right away.

While you are using it

Things you must do

Use **AKYNZEO**® exactly as your doctor or pharmacist has told you.

Tell all the doctors and pharmacists treating you that you are using **AKYNZEO**®.

Tell your doctor immediately if you become pregnant while using **AKYNZEO**®.

Things you must not do

Do not give **AKYNZEO**® to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for more information about **AKYNZEO**®.

Things to be careful of

AKYNZEO® contains sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

AKYNZEO® may cause dizziness or tiredness. You should avoid driving or operating machinery after taking **AKYNZEO**®.

Side effects

Like all medicines, **AKYNZEO®** can cause side effects, although not everybody gets them.

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 anti-depressants 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.

Visit your doctor or pharmacist immediately if you experience any side effects after using.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AKYNZEO®Storage

Store below 30°C.

Keep out of the reach of children.

Disposal

Ask your pharmacist how to dispose of used **AKYNZEO®**.

Product DescriptionWhat it looks like

AKYNZEO® is opaque with a white body and a caramel cap with “HE1” printed on the body.

Packing

AKYNZEO® hard capsule is supplied in aluminum blister containing 1 hard capsule. The aluminium blister is enclosed in a printed carton.

Ingredients

- Active ingredient
300 mg Netupitant and 0.5 mg
Palonosetron hydrochloride

AKYNZEO® contains sucrose and sorbitol.

The gelatin of capsule shell is of bovine origin.

Inactive ingredients

Microcrystalline cellulose, sucrose fatty acid esters, povidone K-30, croscarmellose sodium, purified water, silicon dioxide, sodium stearyl fumarate, magnesium stearate, mono- and di-glycerides of capryl/capric acid, glycerin, polyglyceryl oleate, butylated hydroxyanisole (BHA), gelatin, sorbitol, titanium dioxide, yellow iron oxide, and red iron oxide. It may contain traces of medium-chain triglycerides, lecithin, and denatured ethanol.

Manufacturer

Helsinn Birex Pharmaceuticals Ltd.
Damastown
Mulhuddart
Dublin 15
Ireland

Product Registration Holder

Juniper Biologics Sdn. Bhd.
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Date of revision

Feb 2022 (based on AKYNZEO
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Registration Number

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