

# AKYNZEO®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using AKYNZEO?

AKYNZEO is a combination medicine which contains two active ingredients, netupitant and palonosetron. AKYNZEO is used to prevent nausea (feeling sick) and vomiting caused by cancer chemotherapy in adult patients.

For more information, see Section [1. Why am I using AKYNZEO?](#) in the full CMI.

### 2. What should I know before I use AKYNZEO?

Do not use if you have ever had an allergic reaction to palonosetron, netupitant or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use AKYNZEO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with AKYNZEO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use AKYNZEO?

- The recommended dose is one capsule by mouth, one hour before you start your chemotherapy cycle. More instructions can be found in Section [4. How do I use AKYNZEO?](#) in the full CMI.

### 5. What should I know while using AKYNZEO?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, nurse, dentist or pharmacist you visit that you are using AKYNZEO.</li> <li>• Tell your doctor if you have not taken your medicine exactly as directed.</li> <li>• Tell your doctor if the medicine starts to upset you.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> <li>• Do not take it to treat any other complaints unless your doctor tells you to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use machines or tools until you know how AKYNZEO affects you.</li> <li>• It may cause dizziness, somnolence or fatigue in some people.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your medicine in a cool dry place where it stays below 30°C.</li> </ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects of AKYNZEO are headache, constipation and fatigue. The serious and rare side effects of AKYNZEO are severe stomach pain, slow, fast or irregular heartbeat, dizziness or feeling light headed, or serious allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# AKYNZEO®

**Active ingredients:** netupitant (ne-TU-pi-tant) and palonosetron (pa-la-NOS-etron)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using AKYNZEO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AKYNZEO.**

**Where to find information in this leaflet:**

1. [Why am I using AKYNZEO?](#)
2. [What should I know before I use AKYNZEO?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use AKYNZEO?](#)
5. [What should I know while using AKYNZEO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using AKYNZEO?

**AKYNZEO is a combination medicine which contains two active ingredients. The active ingredients are called netupitant and palonosetron.**

Netupitant belongs to a group of medicines called 'neurokinin-1 (NK1) receptor antagonists'.

Palonosetron belongs to a group of medicines called 'serotonin (5-HT3) receptor antagonists'.

AKYNZEO works by blocking the actions of substances in your body and brain that are thought to cause nausea and vomiting.

**AKYNZEO is used to prevent nausea (feeling sick) and vomiting caused by cancer chemotherapy in adult patients.**

There is not enough information to recommend its use in children under the age of 18 years.

## 2. What should I know before I use AKYNZEO?

### Warnings

**Do not use AKYNZEO if:**

- you are pregnant
- you are allergic to any medicine containing palonosetron or netupitant, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing or a tight feeling in your chest
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

- **you have the rare hereditary problem of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency.**

**Check with your doctor if you:**

- have or have had any of the following medical conditions:
  - constipation
  - bowel obstruction
  - alterations in heart rhythm also known as QT prolongation
  - other heart problems
  - taking any medicines that may induce an abnormal heart rhythm such as amiodarone, nifedipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone
  - liver disease
  - imbalance of certain minerals in your blood such as potassium and magnesium
  - an intolerance to fructose
  - peanut or soya allergy

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take AKYNZEO if you are pregnant or if you are a woman of childbearing potential not using contraception. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed if you are taking AKYNZEO. It is not known whether AKYNZEO passes into breast milk.

### Receiving chemotherapy

It is not recommended to take AKYNZEO in the days following chemotherapy unless you are receiving another chemotherapy cycle.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**AKYNZEO can affect other medicines both during and after treatment. These include:**

- dexamethasone, a steroid used for a variety of conditions
- certain cancer chemotherapy medicines such as docetaxel, etoposide or cyclophosphamide
- certain antibiotics such as erythromycin or moxifloxacin
- midazolam, used as a sedative and to relieve anxiety
- ketoconazole, used to treat fungal infections
- rifampicin, an antibiotic used to treat tuberculosis and other infections
- heart medications such as amiodarone, quinidine and nicardipine
- medicines normally used to treat certain mental and emotional conditions (antipsychotics) such as haloperidol, chlorpromazine, quetiapine and thioridazine
- domperidone, a medicine normally used to treat nausea and vomiting, or certain other gastric problems
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

These medicines may be affected by AKYNZEO or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AKYNZEO.**

#### 4. How do I use AKYNZEO?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information given to you in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

##### How much to take

- The recommended dose is one capsule by mouth, one hour before you start your chemotherapy cycle.

##### When to take AKYNZEO

- Take AKYNZEO approximately one hour prior to starting your chemotherapy cycle.
- Take it with or without food.
- Swallow the capsule whole with a drink of water. If you have trouble swallowing your capsule, tell your doctor.
- If you are taking the sachet, squeeze the entire contents of the sachet directly into the mouth.
- AKYNZEO is a single dose given only on the day of chemotherapy treatment.

- It is not recommended to take AKYNZEO in the days following chemotherapy unless you are receiving another chemotherapy cycle.

##### If you forget to use AKYNZEO

If you forget to take your capsule, contact your doctor for instructions.

##### If you use too much AKYNZEO

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while using AKYNZEO?

##### Things you should do

**Tell your doctor straight away if:**

- for any reason, you have not taken your medicine exactly as directed
- you feel the medicine is not helping to prevent the nausea and vomiting
- the medicine starts to upset you.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using AKYNZEO.

##### Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take it to treat any other complaints unless your doctor tells you to.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how AKYNZEO affects you.**

AKYNZEO may cause dizziness, somnolence or fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

##### Looking after your medicine

- Keep the capsule in the blister pack until it is time to take it.
- If you take the capsule out of the blister it may not keep well.
- Keep your medicine in a cool dry place where it stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

**Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. If it has expired or is damaged, return it to your pharmacist for disposal.

**6. Are there any side effects?**

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking AKYNZEO.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Less serious side effects**

Less serious side effects	What to do
<p><b>Head related:</b></p> <ul style="list-style-type: none"> <li>• headache</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• indigestion, heartburn, loss of appetite, bloating or stomach pain</li> <li>• vomiting</li> </ul> <p><b>Urinary tract related:</b></p> <ul style="list-style-type: none"> <li>• pain on urination</li> </ul> <p><b>General body:</b></p> <ul style="list-style-type: none"> <li>• general weakness</li> <li>• tiredness</li> <li>• generally feeling unwell</li> </ul>	<p><b>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</b></p>

**Serious side effects**

Serious side effects	What to do
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• severe stomach pain</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>• slow, fast or irregular heart beat</li> </ul> <p><b>General body:</b></p> <ul style="list-style-type: none"> <li>• dizziness or feeling light headed</li> </ul>	<p><b>Tell your doctor or nurse as soon as possible if you notice any of these serious side effects.</b></p>

Serious side effects - Allergic reaction	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• swelling of the mouth, face, lips, tongue or throat, which may cause difficulty breathing or swallowing</li> <li>• raised, itchy rash on the skin</li> </ul>	<p><b>Call your doctor as soon as possible, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

**7. Product details**

This medicine is only available with a doctor's prescription.

**What AKYNZEO contains**

<b>Active ingredient (main ingredient)</b>	Netupitant 300mg palonosetron 500 micrograms (as the hydrochloride)
<b>Other ingredients (inactive ingredients)</b>	Capsules: microcrystalline cellulose sucrose laurate povidone croscarmellose sodium

	silicon dioxide sodium stearyl fumarate magnesium stearate glyceryl caprylate / caprate glycerol polyglyceryl-3-dioleate purified water butylated hydroxyanisole gelatin sorbitol special glycerin blend A-810 titanium dioxide (E171) iron oxide yellow, iron oxide red (E172) and iron oxide black (E172) shellac propylene glycol (E1520) ammonium hydroxide (E527)
<b>Potential allergens</b>	Each hard capsule contains 7 mg of sorbitol.  Contains sucrose. It may contain traces of lecithin derived from soya.

Akynzeo does not contain gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

#### **What AKYNZEO looks like**

AKYNZEO is opaque with a white body and a caramel cap with "HE1" printed on the body, supplied in an aluminium blister containing 1 capsule (AUST R 222237).

#### **Who distributes AKYNZEO**

Juniper Biologics Pty Ltd  
Level 14 Suite 3A16 275 Alfred Street  
North Sydney  
NSW 2060  
Australia  
Ph: 1800 281 493

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