

AKYNZEO® IV CONCENTRATED INJECTION

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using AKYNZEO IV?

AKYNZEO IV contains the active ingredients fosnetupitant and palonosetron. AKYNZEO IV 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 IV?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to AKYNZEO IV 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 IV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AKYNZEO IV 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 IV?

- Your doctor will decide how much of this medicine to give you. The recommended dose of AKYNZEO IV is one vial on the first day of your chemotherapy.
- AKYNZEO IV will be given directly into your vein under the supervision of a doctor or nurse.

More instructions can be found in Section [4. How do I use AKYNZEO IV?](#) in the full CMI.

5. What should I know while using AKYNZEO IV?

Things you should do	<ul style="list-style-type: none">Remind any doctor or dentist you visit that you are being treated with AKYNZEO IV.Tell your doctor if you feel the medicine is not helping to prevent the nausea or vomiting.Tell your doctor if the medicine starts to upset you or your symptoms become worse.Tell your doctor if you become pregnant during treatment with this medicine.
Things you should not do	<ul style="list-style-type: none">Do not inject AKYNZEO IV yourself. Always let your doctor or nurse do this.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how AKYNZEO IV affects you.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">Store AKYNZEO IV at 25°C in the original container to protect from light.

For more information, see Section [5. What should I know while being treated with AKYNZEO IV?](#) in the full CMI.

6. Are there any side effects?

Common side effects of AKYNZEO IV are headache, constipation and fatigue. Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you experience shortness of breath, wheezing or difficulty breathing, tightness of the chest, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

AKYNZEO® IV CONCENTRATED INJECTION

Active ingredients: *fosnetupitant and palonosetron*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AKYNZEO IV. **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 IV.**

Where to find information in this leaflet:

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

1. Why am I using AKYNZEO IV?

AKYNZEO IV contains the active ingredients *fosnetupitant and palonosetron*.

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

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

Warnings

Do not use AKYNZEO IV if:

1. you are allergic to fosnetupitant or palonosetron, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
2. you are pregnant.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have constipation
- have a blockage in your bowels
- have alterations in heart rhythm also known as 'QT prolongation'; or any other heart problems
- take any medicines that may cause an abnormal heart rhythm such as amiodarone, nicardipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone
- have liver disease
- have kidney disease

- have an imbalance of certain minerals in your blood such as potassium and magnesium

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 use AKYNZEO IV if you are pregnant or if you are a woman of childbearing potential not using contraception.

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

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

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 IV may increase the effect of the following medicines:

- dexamethasone, a steroid used for a variety of conditions
- certain cancer chemotherapy medicines such as docetaxel, etoposide or cyclophosphamide
- midazolam, used as a sedative and to relieve anxiety
- certain antibiotics such as erythromycin

Medicines that may increase the effect of AKYNZEO IV include:

- ketoconazole, used to treat fungal infections

Medicines that may reduce the effect of AKYNZEO IV include:

- rifampicin, an antibiotic used to treat tuberculosis and other infections

Medicines that may increase the side effects of AKYNZEO IV include:

- medicines used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, and duloxetine
- heart medications such as amiodarone, quinidine and nicardipine
- certain antibiotics such as erythromycin or moxifloxacin

- medicines normally used to treat certain mental and emotional conditions (antipsychotics) such as haloperidol, chlorpromazine and thioridazine quetiapine

- domperidone, a medicine normally used to treat nausea and vomiting, or certain other gastric problems

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 IV.

4. How do I use AKYNZEO IV?

How much to use

- Your doctor will decide how much of this medicine to give you.
- The recommended dose of AKYNZEO IV is one vial on the first day of your chemotherapy.

When to use AKYNZEO IV

- AKYNZEO IV will be given in a single dose, approximately thirty minutes prior to starting your chemotherapy cycle.

How to use AKYNZEO IV

- AKYNZEO IV will be given to you under the supervision of a doctor or nurse experienced in treating cancer.
- It will be given directly into your vein over thirty minutes.
- Each vial is for single use only.

If you forget to use AKYNZEO IV

As AKYNZEO IV is administered under the supervision of your doctor or nurse, it is unlikely that you will miss your dose.

If you use too much (overdose)

As AKYNZEO IV is administered under the supervision of your doctor or nurse, it is unlikely that you will receive too much.

However, if you experience side effects after being treated with AKYNZEO IV, tell your doctor immediately (see section [6. Are there any side effects?](#))

If you think that you have been given too much AKYNZEO IV, you may need urgent medical attention.

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 IV?

Things you should do

Tell your doctor if you feel the medicine is not helping to prevent the nausea and vomiting.

Tell your doctor if the medicine starts to upset you or your symptoms become worse.

Tell your doctor if you become pregnant during treatment with this medicine.

Tell any doctor, dentist or pharmacist you visit that you are using AKYNZEO IV.

Things you should not do

- Do not inject AKYNZEO IV yourself. Your doctor or nurse should always administer AKYNZEO IV for you.

Driving or using machines

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

AKYNZEO IV may cause dizziness, drowsiness 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store AKYNZEO IV below 25°C in the original container to protect from light.

Do not use AKYNZEO IV after the expiry date printed on the carton.

When to discard your medicine

Once opened, your doctor or nurse will discard any unused portion of this medicine.

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.

6. Are there any side effects?

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
General effects <ul style="list-style-type: none">• headache• general weakness• dizziness Digestive system related <ul style="list-style-type: none">• constipation• diarrhoea• upset stomach• stomach pain• flatulence (wind) Heart related <ul style="list-style-type: none">• slower and faster heartbeat	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction related <ul style="list-style-type: none">• 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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. 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 IV contains

Active ingredients (ingredients that make the medicine work)	fosnetupitant palonosetron
Other ingredients (inactive ingredients)	mannitol disodium edetate sodium hydroxide (for pH adjustment) hydrochloric acid (for pH adjustment) Water for Injection

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

What AKYNZEO IV looks like

AKYNZEO IV Concentrated Injection for Solution is a clear, colourless to slightly yellow solution before it is prepared by your doctor or nurse.

It is supplied in a glass vial with a grey stopper and violet cap. Each vial contains enough medicine for one dose.

After preparation, AKYNZEO IV becomes a clear solution. (AUST R 349310).

Who distributes AKYNZEO IV

AKYNZEO IV is supplied in Australia by:

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

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