Applicant : Eurolab (Pty) Ltd
Proprietary name : Akynzeo
Dosage form and strength : Capsules 300 mg/0,5 mg (Netupitant & Palonosetron)
Date of submission : 19 September 2022
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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AKYNZEO™ 300 mg/0,5 mg capsules

Netupitant/palonosetron

Contains sugar

Each capsule contains 20 mg of sucrose and 7 mg of sorbitol

Read all of this leaflet carefully before you start taking AKYNZEO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- AKYNZEO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AKYNZEO is and what it is used for
2. What you need to know before you take AKYNZEO
3. How to take AKYNZEO
4. Possible side effects
5. How to store AKYNZEO
6. Contents of the pack and other information

1. What AKYNZEO is and what it is used for

AKYNZEO is used to help prevent adults with cancer from feeling sick (nausea) or being sick (vomiting) while having cancer treatment called 'chemotherapy'.

2. What you need to know before you take AKYNZEO

Do not take AKYNZEO

- if you are hypersensitive (allergic) to netupitant or palonosetron, or any of the other ingredients of AKYNZEO (listed in section 6)
- if you are pregnant or breastfeeding

Warnings and precautions

Take special care with AKYNZEO:

- if you have a blockage in your gut or you have had constipation in the past
- if you or one of your close relatives has ever had a heart problem called 'QT interval prolongation'
- if you have any other heart problems
- if you have been told you have an imbalance of minerals
- if you have serious liver problems

Children and adolescents

AKYNZEO should not be taken by children.

Other medicines and AKYNZEO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Dexamethasone – can be used to treat inflammatory conditions
- Some chemotherapy medicines such as docetaxel, etoposide or cyclophosphamide
- Erythromycin – to treat bacterial infections
- Midazolam – a sedative used to treat anxiety
- Medicines for depression or anxiety called SSRIs (selective serotonin reuptake inhibitors) such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram or escitalopram
- Medicines for depression or anxiety called SNRIs (serotonin norepinephrine (noradrenaline) reuptake inhibitors) such as venlafaxine or duloxetine
- Ketoconazole – to treat fungal infections
- Rifampicin – to treat tuberculosis (TB) and other infections
- Zidovudine – to treat HIV / AIDS
- Valproic acid – to treat epilepsy
- Morphine – to relieve pain
- Digoxin – to treat heart failure
- Dabigatran – to treat blood clotting
- Colchicine – to treat gout

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take AKYNZEO if you are pregnant or if you are a woman of childbearing potential not using contraception.

Do not breastfeed if you are taking AKYNZEO.

Driving and using machines

You may feel dizzy or tired after taking AKYNZEO. If this happens, do not drive or use any tools or machines, especially if you also take a sedative such as midazolam.

It is not always possible to predict to what extent AKYNZEO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AKYNZEO affects them.

AKYNZEO contains sorbitol, sucrose and soya

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

AKYNZEO may contain traces of lecithin, which comes from soya. If you are allergic to peanuts or soya, see your doctor straight away if you notice any signs of an allergic reaction. The signs may include hives, skin rash, itching, difficulty breathing or swallowing, swollen mouth, face, lips, tongue or throat and sometimes a drop in blood pressure.

3. How to take AKYNZEO

Do not share medicines prescribed for you with any other person.

Always take AKYNZEO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one capsule to be taken 1 hour before you start your chemotherapy cycle.

If you are an elderly person, the same dose (1 capsule) can be taken.

You can take AKYNZEO with or without food.

Your doctor will tell you how long your treatment with AKYNZEO will last.

If you have the impression that the effect of AKYNZEO is too strong or too weak, tell your doctor or pharmacist.

If you take more AKYNZEO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AKYNZEO

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AKYNZEO can have side effects.

Not all side effects reported for AKYNZEO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AKYNZEO, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Allergic reactions (like swelling of the face, mouth, lips, gums, tongue and neck or having trouble breathing)

These are all very serious side effects. If you have them, you may have had a serious reaction to AKYNZEO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache
- Constipation
- Feeling tired

Less frequent side effects

- Infection and inflammation in the bladder (cystitis)
- Low or high level of white blood cells (shown in blood tests)
- High level of lymphocytes – type of white blood cell which help the body fight disease (shown in blood tests)
- Decreased appetite
- Low level of potassium (shown in blood tests)
- Sleep problems
- Sudden nervous breakdown, change in mood
- Dizziness
- Numbness
- Conjunctivitis (a type of eye inflammation)
- Blurred vision
- Spinning sensation (vertigo)
- Heart block
- Irregular heartbeat
- Problems with the muscles in your heart (cardiomyopathy)

- Heart valve disorder (mitral valve incompetence)
- Decreased blood flow to the heart muscle (myocardial ischemia)
- Increased or decreased blood pressure
- Hiccups
- Stomach problems including constipation, stomach ache, difficulty swallowing, diarrhoea, coating of the tongue, indigestion, wind
- Hair loss
- Hives
- Back pain
- Fatigue or lack of energy
- Feeling hot
- Chest pain (not related to the heart)
- Abnormal taste after medicine intake
- High levels of certain enzymes, including blood and liver enzymes (shown in blood tests)
- High levels of creatinine, which measures kidney function (shown in blood tests)
- ECG changes
- High levels of troponin, which indicates heart muscle dysfunction (shown in blood tests)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AKYNZEO.

5. How to store AKYNZEO

- Store all medicines out of reach of children.
- Store at or below 25 °C, protected from moisture and light.
- Keep the blisters in the carton until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AKYNZEO contains

The active substances are netupitant and palonosetron.

Each capsule contains 300 mg of netupitant and 0,5 mg of palonosetron (as palonosetron hydrochloride).

The other ingredients are ammonium hydroxide, black iron oxide, butylated hydroxyanisole, croscarmellose sodium, dehydrated ethanol, gelatine, glycerine (anhydrous), glycerol monocaprylocaproate, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, N-butyl alcohol, povidone K-30, propylene glycol, polyglyceryl dioleate, red iron oxide, shellac glaze (partially esterified), silica colloidal hydrated, sodium stearyl fumarate, sorbitol with glycerine blend, sucrose lauric acid esters, titanium dioxide, yellow iron oxide.

What AKYNZEO looks like and contents of the pack

Hard gelatine capsule size 0, caramel-white with “HE1” printed in black on the white part, containing three tablets round, flat, off-white, plain bevelled edge and one softgel plain, round to oval, opaque light beige.

Aluminium/aluminium blister containing 1 hard capsule. The blister strip is placed in a carton.

Holder of Certificate of Registration

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