

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Fosaprepitant Equity, 150 mg, powder for solution for infusion Fosaprepitant

Contains sugar (anhydrous lactose) 375 mg per vial

Read all of this leaflet carefully before you are given Fosaprepitant Equity

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Fosaprepitant Equity 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 is Fosaprepitant Equity and what it is used for
2. What you need to know before you are given Fosaprepitant Equity
3. How to use Fosaprepitant Equity
4. Possible side effects
5. How to store Fosaprepitant Equity
6. Contents of the pack and other information

1. What Fosaprepitant Equity is and what it is used for

Fosaprepitant Equity contains the active substance fosaprepitant which is converted to aprepitant in your body. It belongs to a group of medicines called "neurokinin 1 (NK₁) receptor antagonists". The brain has a specific area that controls nausea and vomiting. Fosaprepitant Equity works by blocking signals to that area, thereby reducing nausea and vomiting.

Fosaprepitant Equity is used in adults in combination with other medicines to prevent nausea and vomiting caused by chemotherapy (cancer treatment) that is a strong or moderate trigger of nausea and vomiting.

2. What you need to know before you use Fosaprepitant Equity

Fosaprepitant Equity should not be administered to you:

- if you are hypersensitive or allergic to fosaprepitant, aprepitant, or to polysorbate 80 or any of the other ingredients of this medicine (listed in section 6).
- with medicines containing pimozide (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems). Tell your doctor if you are taking these medicines since the treatment must be modified before you start using Fosaprepitant Equity.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or health care provider before being given Fosaprepitant Equity: Special care should be taken with Fosaprepitant Equity:

- if you have liver disease because the liver is important in breaking down the medicine in the body. Your doctor may therefore have to monitor the condition of your liver.

Fosaprepitant Equity should not be given to children.

Other medicines and Fosaprepitant Equity

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Fosaprepitant Equity can affect other medicines both during and after treatment with Fosaprepitant Equity. There are some medicines that should not be taken with Fosaprepitant Equity (such as pimozone, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also “Do not use Fosaprepitant Equity”).

The effects of Fosaprepitant Equity or other medicines might be influenced if you take Fosaprepitant Equity together with other medicines including those listed below. Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- ciclosporin, tacrolimus, sirolimus, everolimus (immunosuppressants),
- alfentanil, fentanyl (used to treat pain),
- quinidine (used to treat an irregular heart beat),
- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- corticosteroids (such as dexamethasone & methylprednisolone),
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer),
- warfarin, acenocoumarol (blood thinners; blood tests may be required),
- tolbutamide (a medicine used to treat diabetes).
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep),
- birth control medicines which can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones may not work adequately when taken together with Fosaprepitant Equity. Another or additional non-hormonal form of birth control should be used during treatment with Fosaprepitant Equity and for up to 2 months after using Fosaprepitant Equity,
- anti-anxiety medicines (such as alprazolam),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),
- ketoconazole,

- itraconazole, voriconazole, posaconazole (antifungals),
- protease inhibitors (used to treat HIV infections),
- diltiazem (a medicine used to treat high blood pressure),
- rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- paroxetine (antidepressant).

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before using Fosaprepitant Equity.

Do not use Fosaprepitant Equity if you are pregnant or breastfeeding your baby.

Driving and using machines

It should be taken into account that some people get dizzy and get sleepy after using Fosaprepitant Equity. If you get dizzy or get sleepy, avoid driving or using machines after using this medicine (see 'Possible side effects').

It is not always possible to predict to what extent Fosaprepitant Equity may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which Fosaprepitant Equity affects you.

3. How to use Fosaprepitant Equity

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

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

Fosaprepitant Equity will be given 150 mg on Day 1 only.

Day 1 (Day of chemotherapy): Fosaprepitant Equity will be given to you into the vein approximately 30 minutes before you start your chemotherapy treatment. Your doctor may ask you to take other medicines including a corticosteroid (such as dexamethasone) and a '5HT₃ antagonist' (such as ondansetron) for preventing nausea and vomiting.

For single use only. Discard any unused portion.

You will not be expected to give yourself Fosaprepitant Equity. It will be given to you by a person who is qualified to do so.

If you are given more Fosaprepitant Equity than you should

Since a healthcare provider will administer FOSAMEND, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Fosaprepitant Equity

Since a healthcare provider will administer Fosaprepitant Equity, it is unlikely that the dose will be missed.

4. Possible side effects

Fosaprepitant Equity can have side effects.

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

If any of the following happens, stop using Fosaprepitant Equity and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

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

Tell your doctor immediately if you notice any of the following:

- infusion site reactions (ISR) at or near the infusion site. Most severe ISR have happened with a certain type of chemotherapy medicine that can burn or blister your skin (vesicant) with side effects, including pain, swelling and redness. Death of skin tissue (necrosis) has happened in some people getting this type of chemotherapy medicine
- slow heartbeat, heart and blood vessel disease
- serious disorder that affects the skin, mucous membrane, genitals and eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis (rare severe skin reaction))

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite
- headache
- hiccups
- constipation, indigestion
- tiredness
- increased amount of liver enzymes in your blood

Less frequent side effects:

- bacterial infection, fungal infection
- fever with increased risk of infection, lowering of red blood cells
- intense thirst despite drinking plenty of fluids
- anxiousness, euphoria (feeling of extreme happiness), disorientation
- sleepiness, difficulty thinking, lack of energy, taste disturbance
- eye discharge and itching
- ringing in the ear
- reddening of the face/skin, hot flush
- cough, mucus in back of throat, throat irritation, sneezing, sore throat
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind
- severe constipation, stomach ulcer, inflammation of the small intestine and colon, sores in mouth, bloating
- sensitivity of the skin to sun, excessive sweating, acne, oily skin, sores on skin, itching rash
- hives
- muscle spasms, muscle weakness
- frequent urination, passing more urine than normal
- chest discomfort, swelling, change in the manner of walking
- decreased muscle strength
- lowering of white blood cells, low sodium levels in the blood, weight loss
- presence of sugar or blood in urine, red blood cells (RBC) can be present in urine
- high alkaline phosphatase levels
- increased blood pressure
- redness of the skin, either in a limited area or all over.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Fosaprepitant Equity.

5. How to store Fosaprepitant Equity

Store all medicines out of reach of children.

Store at 2 °C to 8 °C (in refrigerator).

Do not use after the expiry date shown on the box.

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 Fosaprepitant Equity contains

The active substance is fosaprepitant. Each vial contains fosaprepitant dimeglumine equivalent to 150 mg fosaprepitant. After reconstitution and dilution 1 ml of solution contains 1 mg fosaprepitant (1 mg/ml).

The other ingredients are: disodium edetate, lactose anhydrous, hydrochloric acid (for pH adjustment), polysorbate 80, sodium hydroxide (for pH adjustment) and water for injection.

What Fosaprepitant Equity looks like and contents of the pack

White to off-white lyophilised cake or powder.

Fosaprepitant Equity is packed in a clear tubular glass vials stoppered with grey bromobutyl rubber closure and sealed with flip top aluminium seals.

Pack sizes: 1 or 10 vials.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene

Pretoria

0157

+27 (0)12 345 1747

This leaflet was last revised in

06 May 2025

Registration /Application number

56/5.7.2/1178