

PATIENT INFORMATION LEAFLET

FOSAPREPITANT CIPLA

Scheduling status

S4

FOSAPREPITANT CIPLA (150 mg Lyophilised powder for Solution for Infusion)

Fosaprepitant Dimeglumine

Contains Sugar (Lactose Anhydrous 375 mg)

Read all of this leaflet carefully before you are given FOSAPREPITANT CIPLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse, or other health care provider.

What is in this leaflet

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

1. What FOSAPREPITANT CIPLA is and what it is used for

FOSAPREPITANT CIPLA contains the active substance Fosaprepitant dimeglumine which is converted to aprepitant in the body. Aprepitant belongs to a group of medicines called

"neurokinin 1 (NK₁) receptor antagonists". The brain has a specific area that controls nausea (feeling sick) and vomiting. FOSAPREPITANT CIPLA works by blocking signals to that area of the brain, thereby reducing nausea and vomiting.

FOSAPREPITANT CIPLA is used in combination with other medicines to prevent nausea (feeling sick) and vomiting caused by chemotherapy (cancer treatment).

Doctor has prescribed FOSAPREPITANT CIPLA for the prevention of nausea and vomiting triggered by cancer chemotherapy treatment.

2. What you need to know before you are administered FOSAPREPITANT CIPLA

FOSAPREPITANT CIPLA should not be administered to you

- if you are hypersensitive (allergic) to aprepitant, polysorbate 80 or any other ingredients other ingredients of FOSAPREPITANT CIPLA (listed in **section 6**).
- If you are pregnant or breastfeeding your baby.
- If you are using medication containing pimozide (medicines used to treat psychiatric illnesses), terfenadine and astemizole (medicines used for hay fever and other allergic conditions), cisapride (used for treating digestive problems). Taking FOSAPREPITANT CIPLA with these medicines could result in **serious or life-threatening problems**.

Warnings and precautions

Tell your doctor or health care provider before being given FOSAPREPITANT CIPLA:

- If you have had any past or present liver disease
- If you have any allergies
- If you are taking or plan to take any medicine, even those you get without a prescription or traditional medicines

Children and adolescents

FOSAPREPITANT CIPLA should not be given to children, as it has not been adequately studied in children.

Other medicines and FOSAPREPITANT CIPLA

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

FOSAPREPITANT CIPLA can affect other medicines both during and after treatment with FOSAPREPITANT CIPLA. There are some medicines that should not be taken with FOSAPREPITANT CIPLA (such as pimozide, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also '**FOSAPREPITANT CIPLA should not be administered to you**' section).

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

- birth control medicines which include birth control pills, skin patches, implants, and certain intrauterine devices (IUDs) that release hormones, may not work adequately when taken together with FOSAPREPITANT CIPLA. Another or additional non-hormonal form of birth control should be used during treatment with FOSAPREPITANT CIPLA and for up to 1 month after using FOSAPREPITANT CIPLA,
- ciclosporin, tacrolimus, sirolimus, everolimus (medicines used to suppress, or reduce the strength of the body's immune system),
- alfentanil, fentanyl (medicines used to treat pain),
- quinidine (medicines used to treat an irregular heartbeat),

- irinotecan, etoposide, vinorelbine, docetaxel, ifosfamide, cyclophosphamide and paclitaxel (medicines used to treat cancer),
- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (medicines used for treatment of migraines),
- warfarin (medicines used to reduce blood clot formation; blood tests may be required), rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (medicine used to treat depression and epilepsy),
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep),
- St. John's Wort (herbal preparation used to treat depression),
- protease inhibitors (medicines used to treat HIV infections),
- ketoconazole except shampoo (used to treat Cushing's syndrome – when the body produces an excess of cortisol),
- itraconazole (antifungals),
- nefazodone (medicine used to treat depression),
- diltiazem (medicine used to treat high blood pressure),
- corticosteroids, such as dexamethasone (medicines to treat different inflammation conditions),
- anti-anxiety medicines (such as alprazolam),
- tolbutamide (a medicine used to treat diabetes).

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 health care provider for advice before taking this medicine.

For information regarding birth control, see '**Other medicines and FOSAPREPITANT CIPLA**' section.

FOSAPREPITANT CIPLA should not be given to women who are pregnant or who are breastfeeding their babies.

Driving and using machines

There are side effects reported for FOSAPREPITANT CIPLA that may affect the ability to drive or operate machines. If you get dizzy or get sleepy, avoid driving or using machines after been administered FOSAPREPITANT CIPLA (see '**Possible side effects**' section).

FOSAPREPITANT CIPLA contains sugar in the form of Lactose Anhydrous

If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before your administered FOSAPREPITANT CIPLA.

3. How to take FOSAPREPITANT CIPLA

You will not be expected to administer FOSAPREPITANT CIPLA yourself. It will be administered to you by a person who is qualified to do so. Through vein from intravenous drip.

If you take more FOSAPREPITANT CIPLA you should

Since a health care provider will administer FOSAPREPITANT CIPLA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use FOSAPREPITANT CIPLA

Since a health care provider will administer FOSAPREPITANT CIPLA, it is unlikely that the dose will be missed.

4. Possible side effects

FOSAPREPITANT CIPLA can have side effects.

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

If any of the following happens, stop taking FOSAPREPITANT CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hives (raised itchy bumps on the skin), rash, itching, redness of face/skin, swelling of the face, throat, tongue and lips, difficulty in breathing or swallowing, or a serious decrease of blood pressure; these are signs of a serious allergic reaction.
- 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.

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

Tell your doctor if you notice any of the following.

Frequent side effects:

- Hiccups,

- increased amount of liver enzymes in your blood,
- constipation, indigestion,
- headache,
- tiredness,
- loss of appetite.

Less Frequent side effects:

- dizziness, sleepiness,
- acne, rash,
- anxiousness,
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind,
- increased painful or burning urination,
- weakness, generally feeling unwell,
- reddening of the face/skin, hot flush,
- fast or irregular heartbeats, blood pressure increased,
- fever with increased risk of infection, lowering of red blood cells,
- infusion site pain, infusion site redness, infusion-site itching, infusion site vein inflammation.
- difficulty thinking, lack of energy, taste disturbance,
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin, itching rash, Stevens-Johnson syndrome/toxic epidermal necrolysis (rare severe skin reaction),
- euphoria (feeling of extreme happiness), disorientation,
- bacterial infection, fungal infection,
- severe constipation, stomach ulcer, inflammation of the small intestine and colon, sores in mouth, bloating,

- frequent urination, passing more urine than normal, presence of sugar or blood in urine,
- chest discomfort, swelling, change in the manner of walking,
- cough, mucus in back of throat, throat irritation, sneezing, sore throat,
- eye discharge and itching,
- ringing in the ear,
- muscle spasms, muscle weakness,
- excessive thirst,
- slow heartbeat, heart, and blood vessel disease,
- lowering of white blood cells, low sodium levels in the blood, weight loss,
- hardening of site of infusion.

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 Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of FOSAPREPITANT CIPLA.

5. How to store FOSAPREPITANT CIPLA

Store all medicines out of reach of children.

The centre where you receive your treatment will store and dispose of FOSAPREPITANT CIPLA on your behalf.

6. Contents of the pack and other information

What FOSAPREPITANT CIPLA contains

- The active substance is, Fosaprepitant Dimeglumine
Each 10 mL vial of FOSAPREPITANT CIPLA contains 245,3 mg Fosaprepitant Dimeglumine equivalent to 150 mg of Fosaprepitant.
When reconstituted (150 mg of Fosaprepitant in 150 mL 0,9 % Sodium chloride Injection), yields a final concentration of 1 mg/mL Fosaprepitant solution for infusion.
- The other ingredients are, Disodium edetate, hydrochloric acid, lactose anhydrous, polysorbate – 80, sodium hydroxide pellets, water for Injection

Contains sugar (Anhydrous lactose 375 mg).

What FOSAPREPITANT CIPLA looks like and contents of the pack

FOSAPREPITANT CIPLA is a white to off white lyophilised cake or powder for solution for Infusion,

packed in 10 mL clear tubular Type I glass vial, with 13 mm grey Bromo butyl double slotted rubber stopper and sealed with aluminium flip-off seal with green colour polypropylene disc.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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