FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EMETEND 150 mg

Powder for solution for infusion

Fosaprepitant

Contains sugar (lactose)

Read all of this leaflet carefully before you are given EMETEND 150 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What EMETEND 150 mg is and what it is used for

- EMETEND 150 mg contains the active substance fosaprepitant.
- It is converted to aprepitant in your body.
- It belongs to a group of medicines called “neurokinin 1 (NK_1) receptor antagonists”.
- The brain has a specific area that controls nausea and vomiting. EMETEND 150 mg works by blocking signals to that area, thereby reducing nausea and vomiting.
- It is used in combination with other medicines to prevent nausea and vomiting caused by

cancer treatment (chemotherapy).

2. What you need to know before you use EMETEND 150 mg

EMETEND 150 mg should not be administered to you:

- if you are hypersensitive (allergic) to fosaprepitant or any of the other ingredients of EMETEND 150 mg (listed in section 6).
- if you are taking pimozide (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions) or cisapride (used for treating digestive problems).
- If you are pregnant or breastfeeding.
- If you are under 18 years of age.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with EMETEND 150 mg:

- if you have liver disease because the liver is important in breaking down the medicine in the body. Your doctor may have to monitor the condition of your liver.
- if you experience redness of the skin or difficulty in breathing whilst or soon after being administered EMETEND 150 mg.

Children and adolescents

EMETEND 150 mg should not be given to children and adolescents under 18 years of age, as it has not been studied in this population.

Other medicines and EMETEND 150 mg

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- An infusion of EMETEND 150 mg can affect other medicines and taking other medicines while using fosaprepitant might affect how fosaprepitant works.
- The effects of EMETEND 150 mg or other medicines may be increased or decreased when

taken together.

- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
    - birth control medicines as they may not work effectively when taken together with fosaprepitant. Additional non-hormonal birth control should be used while on treatment with fosaprepitant and for one month after treatment
    - ciclosporin, tacrolimus, sirolimus, everolimus (medicines that decrease the body's immune response)
    - alfentanil, fentanyl (used to treat pain)
    - quinidine (used to treat irregular heartbeat)
    - irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer)
    - medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
    - warfarin, acenocoumarol (blood thinners; blood tests may be required),
    - rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
    - phenytoin (a medicine used to treat seizures),
    - carbamazepine (used to treat depression and epilepsy
    - midazolam, triazolam, phenobarbitone (medicines used to produce calmness or help you sleep),
    - St. John's Wort (a herbal preparation used to treat depression)
    - protease inhibitors (used to treat HIV infections)
    - ketoconazole except shampoo (used to treat Cushing's syndrome – when the body produces an excess of cortisol),
    - itraconazole, voriconazole, posaconazole (antifungals),
    - nefazodone (used to treat depression),
    - diltiazem (a medicine used to treat high blood pressure),
    - corticosteroids (such as dexamethasone, methylprednisolone),
    - anti-anxiety medicines (such as alprazolam),

- tolbutamide (a medicine used to treat diabetes)
- 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 taking EMETEND 150 mg.
- You should not use EMETEND 150 mg during pregnancy.
- For information regarding birth control see “Other medicines and EMETEND 150 mg”.
- It is not known whether fosaprepitant is excreted in human milk; therefore, breast-feeding is not recommended during treatment with this medicine. It is important that you tell your doctor if you are breast-feeding or are planning to breast-feed before receiving EMETEND 150 mg.

Driving and using machines

- EMETEND 150 mg may cause dizziness and fatigue.
- It is not always possible to predict to what extent EMETEND 150 mg 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 EMETEND 150 mg affects them.

3. How to use EMETEND 150 mg

- Do not share medicines prescribed for you with any other person.
- EMETEND 150 mg will be given to as an intravenous infusion (a drip).
- The powder will be reconstituted and diluted before use.
- You will not be expected to give yourself EMETEND 150 mg . It will be given to you by a person who is qualified to do so.

If you take more EMETEND 150 mg than you should

Since a healthcare professional will administer EMETEND 150 mg, he/she will control the

dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take EMETEND 150 mg

Since a healthcare professional will administer EMETEND 150 mg, it is unlikely that the dose will be missed.

4. Possible side effects

- EMETEND 150 mg can have side effects.
- Not all side effects reported for EMETEND 150 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EMETEND 150 mg, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking EMETEND 150 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:
    - hives, rash, itching,
    - difficulty breathing or swallowing,
    - or a serious decrease of blood pressure
- These are all very serious side effects. If you have them, you may have had a serious reaction to EMETEND 150 mg. You may need urgent medical attention or hospitalisation.
- Other side effects that have been reported:
    - <u>Frequent side effects</u>
        - constipation, indigestion,
        - headache,
        - tiredness,
        - loss of appetite,
        - hiccups,
        - increased amount of liver enzymes in your blood
    - <u>Less frequent side effects</u>

- dizziness, sleepiness,
- acne, rash, excessive sweating, Stevens-Johnson syndrome
- 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.
- fungal and bacterial infection
- extreme thirst
- feeling disorientated
- difficulty swallowing
- eye infection
- sensation of ringing in the ears
- sneezing, coughing, postnasal drip, throat irritation
- stomach distension, hard faeces
- muscle weakness / spasms
- water retention, discomfort in the chest
- increased amount of liver and blood enzymes
- changes in blood electrolytes, decrease in weight, glucose in urine

o Unknown frequency side effects

- allergic reactions / anaphylactic reaction (skin rash, difficulty breathing, shock)

- skin itching / hives (itchy, red, raised bumps on the skin)
- immediate allergic reactions

- 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>. This includes any possible side effects not listed in this leaflet. 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. By reporting side effects, you can help provide more information on the safety of EMETEND 150 mg.

5. How to store EMETEND 150 mg

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C).
- From a microbiological point of view, the medicinal product should be used immediately.
- If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 48 hours at 20 to 25 °C.

6. Contents of the pack and other information

What EMETEND 150 mg 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, polysorbate 80, anhydrous lactose, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What EMETEND 150 mg looks like and contents of the pack

- EMETEND 150 mg is a white to off white lyophilized solid.

- The powder is contained in a 10 ml 13 mm clear flat bottom tubular glass vial with a grey siliconised rubber stopper and aluminium seal with orange coloured flip off plain top.
- Pack size: 1 vial

HOLDER OF CERTIFICATE OF REGISTRATION

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