PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

EASAN 150 mg powder for solution for infusion

Fosaprepitant

Contains sugar: lactose monohydrate 395 mg per vial

Read all of this leaflet carefully before you are given EASAN

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

What is in this leaflet

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

1. What EASAN is and what it is used for

EASAN contains the active substance fosaprepitant which 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. EASAN works by blocking signals to that area, thereby reducing nausea and vomiting.

EASAN 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 receive EASAN

EASAN should not be administered to you:

- If you are hypersensitive (allergic) to fosaprepitant, or any of the other ingredients of EASAN (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). Using these medicines with EASAN can cause serious or life-threatening reactions. Tell your doctor if you are taking these medicines since the treatment must be modified before you start using EASAN.
- If you are pregnant or breastfeeding.
- If you are under 18 years of age.

Warnings and precautions

Take special care with EASAN:

- 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.
- if you are taking or using birth control medicines (see ‘Other medicines and EASAN’).
- if you are taking warfarin or other medicines to thin your blood (see ‘Other medicines and EASAN’).

- If you experience skin reactions or irritation at the injection site (see 'Possible side effects').

Children and adolescents

EASAN should not be administered to children under 18 years of age.

Other medicines and EASAN

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

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

The effects of EASAN or other medicines might be influenced if you take EASAN 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 can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones may not work adequately when taken together with EASAN. Another or additional non-hormonal form of birth control should be used during treatment with EASAN and for up to 2 months after using EASAN.
- ciclosporin, tacrolimus, sirolimus, everolimus (immunosuppressants).
- alfentanil, fentanyl (used to treat pain).
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer).
- quinidine (used to treat an irregular heartbeat).

- 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, phenobarbital (medicines used to produce calmness or help you sleep).
- St. John's Wort (an herbal preparation used to treat depression).
- protease inhibitors (used to treat HIV infections).
- itraconazole, voriconazole, posaconazole (antifungals).
- nefazodone (used to treat depression).
- diltiazem (a medicine used to treat high blood pressure).
- corticosteroids (such as dexamethasone or methylprednisolone).
- anti-anxiety medicines (such as alprazolam).
- tolbutamide (a medicine used to treat diabetes).

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 receiving this medicine.

EASAN should not be administered during pregnancy and breastfeeding.

For information regarding birth control, see 'Other medicines and EASAN.

It is not known whether EASAN is excreted in human milk; therefore, breast-feeding is not recommended during treatment with EASAN.

Driving and using machines

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

EASAN contains lactose monohydrate

EASAN contains lactose monohydrate. If you have been told that you have an intolerance to some sugars, you should not use EASAN.

3. How to use EASAN

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

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

The usual dose in adults (18 years of age and older) is EASAN 150 mg on Day 1 (day of chemotherapy).

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. Check with your doctor or pharmacist if you are not sure.

The powder is reconstituted and diluted before use. The solution for infusion is given to you by a health care professional, such as a doctor or nurse, via an intravenous infusion (a drip) approximately 30 minutes before you start the chemotherapy treatment in adults.

Your doctor will tell you how long your treatment with EASAN will last. If you have the impression that the effect of EASAN is too strong or too weak, tell your doctor or pharmacist.

If you receive more EASAN than you should

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

If you missed a dose of EASAN

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

4. Possible side effects

EASAN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- Stevens-Johnson syndrome/toxic epidermal necrolysis (rare severe skin reaction)
- rash or itching,
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital 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.

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

Tell your doctor if you notice any of the following:

Frequent

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

Less frequent

- dizziness, sleepiness,
- acne, rash, hives
- 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, infusion site duration (pain at the injection site),
- difficulty thinking, lack of energy, taste disturbance,
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin,
- 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, pharmacist or nurse. You can also report side effects to SAHPRA via 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 EASAN.

5. How to store EASAN

Store all medicines out of reach of children.

- Store in a refrigerator at 2 – 8 ˚C.
- The reconstituted and diluted solution is stable for 24 hours at 25 °C.
- Do not use after the expiry date stated on the label / 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 EASAN contains

- Each EASAN vial contains 245,3 mg of fosaprepitant dimeglumine equivalent to 150 mg of fosaprepitant free acid.

  Contains sugar: lactose monohydrate 395 mg per vial.
- The other ingredients are edetate disodium (E386), lactose monohydrate, polysorbate 80 (E433), hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injection.

What EASAN looks like and contents of the pack

EASAN is a white or off-white block-shaped solid or powder.

EASAN is packed 10 ml colourless transparent injection vials made of neutral borosilicate glass tubing, with grey rubber closure and aluminium cap.

Pack size: one vial per cardboard carton.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

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This leaflet was last revised in

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Registration number

550659

Access to the corresponding Professional Information

To be confirmed.