

Package leaflet: Information for the user

APRITANT IV INJECTION (Fosaprepitant for Injection 150 mg/ Vial)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What APRITANT IV is and what it is used for
2. What you need to know before you use APRITANT IV
3. How to use APRITANT IV
4. Possible side effects
5. What should I do in case of an overdose?
6. How to store APRITANT IV
7. Contents of the pack and other information

1. What is APRITANT IV and what it is used for?

APRITANT IV (fosaprepitant dimeglumine) is to be given intravenously by your doctor and it contains 150 mg of fosaprepitant as the active ingredient.

In addition, APRITANT IV contains the following inactive ingredients: edetate disodium, polysorbate 80, lactose anhydrous, sodium hydroxide and/or hydrochloric acid.

APRITANT IV is a member of a class of medicines called neurokinin 1 (NK1) receptor antagonists that is used **ALONG WITH OTHER MEDICINES** to prevent and control nausea (sick feeling in the back of throat and stomach) and vomiting (throwing up) caused by your cancer chemotherapy treatment.

Why my doctor has prescribed APRITANT IV

Your doctor has prescribed APRITANT IV for the prevention of nausea and vomiting associated with your cancer therapy treatment.

2. What you need to know before you use APRITANT IV

Do not use APRITANT IV:

If you are allergic to fosaprepitant, aprepitant, or to polysorbate 80 or any of the other ingredients

(listed in section 7).

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 your treatment must be modified before you start using APRITANT IV.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using APRITANT IV

Before treatment with APRITANT IV, tell your doctor if you have liver disease because your liver is important in breaking down the medicine in your body. Your doctor may therefore have to monitor the condition of your liver.

Tell your doctor about any of the following that apply to you:

- any past or present medical problems.
- any allergies.
- all medicines that you are taking or plan to take, even those you can get without a prescription or herbal products.

Children and adolescents

APRITANT IV is not for use in children and adolescents under 18 years of age.

Use in the elderly

No dosage adjustment is necessary for elderly patients.

Other medicines and APRITANT IV

APRITANT IV can affect other medicines both during and after treatment with APRITANT IV. There are some medicines that should not be taken with APRITANT IV (such as pimozide, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also 'Do not use APRITANT IV'). Taking APRITANT IV with these medications could result in serious or life threatening problems.

The effects of APRITANT IV or other medicines might be influenced if you take APRITANT IV 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 APRITANT IV. Another or additional non-hormonal form of birth control should be used during treatment with APRITANT IV and for up to 2 months after using APRITANT IV.

- Cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
- Alfentanil, fentanyl (used to treat pain),
- Quinidine (used to treat an irregular heart beat),
- Irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer),
- Medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- Warfarin (A blood thinner),
- Rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- Phenytoin (a medicine used to treat seizures),
- Carbamazepine (used to treat depression and epilepsy),
- Midazolam, 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),
- Ketoconazole (except shampoo), itraconazole (antifungals),
- Nefazodone (used to treat depression),
- Diltiazem (a medicine used to treat high blood pressure),
- Corticosteroids (such as dexamethasone),
- Anti-anxiety medicines (such as alprazolam),
- Tolbutamide (a medicine used to treat diabetes)

Tell your doctor about any other medicines or herbal medicines you are taking, have recently taken, or might take.

Pregnancy and breast-feeding

You should not use APRITANT IV during pregnancy unless clearly necessary. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine.

For information regarding birth control, see 'Other medicines and APRITANT IV'

It is not known whether APRITANT IV is excreted in human milk; therefore, breast-feeding is not recommended during treatment with APRITANT IV. It is important that you tell your doctor if you are breast-feeding or are planning to breast-feed before receiving APRITANT IV.

Driving and using machines

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

APRITANT IV contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

3. How to use APRITANT IV

The recommended dose of APRITANT IV is 150 mg fosaprepitant on Day 1 (day of chemotherapy).

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 your chemotherapy treatment. Your doctor will 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking APRITANT IV and see a doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment:

- Hives, rash, itching, difficulty breathing or swallowing (frequency not known, cannot be estimated from the available data); these are signs of an allergic reaction.

Other side effects that have been reported are listed below.

Common side effects (may affect up to 1 in 10 people) are:

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

Uncommon side effects (may affect up to 1 in 100 people) are:

- 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.

Rare side effects (may affect up to 1 in 1,000 people) are:

- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. What should I do in case of an overdose?

If you take more than the prescribed dosage, contact your doctor immediately.

6. How to store APRITANT IV

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The first 2 numbers indicate the month; the next 4 numbers indicate the year.

Store in a refrigerator (2°C - 8°C).

The reconstituted and diluted solution is stable for 24 hours at 25°C.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

7. Contents of the pack and other information

What APRITANT IV 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, Lactose anhydrous, Sodium hydroxide (for pH adjustment) and/or Hydrochloric acid diluted (for pH adjustment).

What APRITANT IV looks like and contents of the pack

APRITANT IV is a white to off-white lyophilized cake or powder for solution for infusion.

The powder is contained in a 10 mL tubular (USP) Type I clear glass vial with a 13 mm bromobutyl double slotted rubber stopper and sealed with aluminium seal having polypropylene disc.

The appearance of the product after reconstitution is a clear colorless to pale yellow colour solution free from visible particle matter.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C (77°F). From a microbiological point of view, the 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 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Each vial contains 150 mg of fosaprepitant.

Pack sizes: 1 or 10 vials.

Not all pack sizes may be marketed.

Manufactured by

MSN Laboratories Private Limited

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