Patient Information

Fosaprepitant
(FOS a PREP i tant)
for Injection

Read this Patient Information before you start receiving fosaprepitant for injection and each time you are scheduled to receive fosaprepitant for injection. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is Fosaprepitant for Injection?

Fosaprepitant for injection is a prescription medicine used with other medicines that treat nausea and vomiting in patients 18 years of age and older to prevent nausea and vomiting caused by certain anti-cancer (chemotherapy) medicines..

- Fosaprepitant for injection is not used to treat nausea and vomiting that you already have.
- It is not known if fosaprepitant for injection is safe and effective in children less than 6 months of age.

Who should not receive Fosaprepitant for Injection?

Do not receive Fosaprepitant for Injection if you:

- are allergic to fosaprepitant, aprepitant, or any of the ingredients in fosaprepitant for injection. See the end of this leaflet for a complete list of the ingredients in fosaprepitant for injection.
- are taking pimozide (ORAP®)

What should I tell my healthcare provider before receiving Fosaprepitant for Injection?

Before receiving Fosaprepitant for Injection, tell your healthcare provider if you:

- have liver problems
- are pregnant or plan to become pregnant. It is not known if fosaprepitant for injection can harm your unborn baby.
    - Women who use birth control medicines containing hormones to prevent pregnancy (birth control pills, skin patches, implants, and certain IUDs) should also use a backup method of birth control that does not contain hormones, such as condoms and spermicides, during treatment with fosaprepitant for injection and for 1 month after receiving fosaprepitant for injection.
- are breastfeeding or plan to breastfeed. It is not known if fosaprepitant for injection passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive fosaprepitant for injection.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Fosaprepitant for injection may affect the way other medicines work, and other medicines may affect the way fosaprepitant for injection works, causing serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How will I receive Fosaprepitant for Injection?
Adults 18 years of age and older:
Fosaprepitant for injection will be given on Day 1 of chemotherapy treatment. It will be given to you by intravenous (IV) infusion in your vein about 50 to 60 minutes before you start your chemotherapy treatment.

If you take the blood thinner medicine warfarin sodium (COUMADIN®, JANTOVEN®), your healthcare provider may do blood tests after you receive fosaprepitant for injection to check your blood clotting.

What are the possible side effects of Fosaprepitant for Injection?
Fosaprepitant for Injection may cause serious side effects, including:

- **Serious allergic reactions.** Allergic reactions can happen with fosaprepitant for injection and may be serious. Tell your doctor or nurse right away if you have hives, rash, itching, flushing or redness of your face or skin, trouble breathing or swallowing, dizziness, a rapid or weak heartbeat, or you feel faint during or soon after you receive fosaprepitant for injection, as you may need emergency medical care.
- Severe skin reactions which may include rash, skin peeling, or sores may occur.
- Infusion site reactions (ISR) at or near the infusion site have happened with fosaprepitant for injection.

  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. Most ISR can happen with the first, second, or third dose and some can last up to 2 weeks or longer. Tell your healthcare provider right away if you get any infusion site side effects.

In adults, the most common side effects of fosaprepitant for injection include:

- tiredness
- diarrhea
- low white blood cell and red blood cell counts
- weakness
- feeling weak or numb in your arms and legs
- painful, difficult, or changes in your digestion (dyspepsia)
- urinary tract infection
- pain in your arms and legs

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of fosaprepitant for injection. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

General information about the safe and effective use of Fosaprepitant for Injection.
If you would like more information about fosaprepitant for injection, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about fosaprepitant for injection that is written for health professionals. For more information about fosaprepitant for injection call 1-800-399-256 or go to www.lupinpharmaceuticals.com.

What are the ingredients in Fosaprepitant for Injection?
Active ingredient: fosaprepitant dimeglumine

Inactive ingredients: edetate disodium, lactose anhydrous, polysorbate 80, sodium hydroxide and/or hydrochloric acid (for pH adjustment)

Pediatric use information is approved for Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.'s Emend (fosaprepitant) for injection. However, due to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
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United States.

Manufactured by:
Gland Pharma Limited
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INDIA.

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