Patient Information EMEND® (EE mend) (fosaprepitant dimeglumine) for Injection

Read this Patient Information before you start receiving EMEND for Injection and each time you are scheduled to receive EMEND 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 EMEND for Injection?

EMEND for Injection is a prescription medicine used with other medicines that treat nausea and vomiting in adults to prevent nausea and vomiting caused by certain anti-cancer (chemotherapy) medicines.

- EMEND for Injection is not used to treat nausea and vomiting that you already have.
- It is not known if EMEND for Injection is safe and effective in children.

Who should not receive EMEND for Injection?

Do not receive EMEND for Injection if you:

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

What should I tell my healthcare provider before receiving EMEND for Injection? Before receiving EMEND for Injection, tell your healthcare provider if you:

- have liver problems
- are pregnant or plan to become pregnant. It is not known if EMEND 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 EMEND for Injection and for 1 month after receiving EMEND for Injection.
- are breastfeeding or plan to breastfeed. It is not known if EMEND for Injection passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive EMEND for Injection.

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

EMEND for Injection may affect the way other medicines work, and other medicines may affect the way EMEND 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 EMEND for Injection?

EMEND for Injection is given on Day 1. It will be given to you by intravenous (IV) infusion in your vein about 30 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 EMEND for Injection to check your blood clotting.

What are the possible side effects of EMEND for Injection?

EMEND for Injection may cause serious side effects, including:

• **Serious allergic reactions.** Allergic reactions can happen with EMEND 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, or trouble breathing or swallowing during or soon after you receive EMEND for Injection, as you may need emergency medical care.

Severe skin reactions which may include rash, skin peeling, or sores may occur.

The most common side effects of EMEND 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

Infusion-site side effects with EMEND for Injection may include pain, hardening, redness or itching at the site of infusion. Swelling (inflammation) of a vein caused by a blood clot can also happen at the infusion site. Tell your healthcare provider if you get any infusion-site side effects.

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 EMEND 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-FDA-1088.

General information about the safe and effective use of EMEND for Injection

If you would like more information about EMEND for Injection, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about EMEND for Injection that is written for health professionals. For more information about EMEND for Injection call 1-800-622-4477 or go to www.emend.com.

What are the ingredients in EMEND for Injection?

Active ingredient: fosaprepitant dimeglumine

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

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of **MERCK & CO., INC.,** Whitehouse Station, NJ 08889, USA Manufactured by: Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Highway, Greenville, NC 27834, USA For patent information: www.merck.com/product/patent/home.html

The brands listed in the above sections "Who should not take EMEND for Injection?" and "How will I receive EMEND for Injection?" are the registered trademarks of their respective owners and are not trademarks of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

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