Patient Information EMEND[®] (EE mend) (fosaprepitant) 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 patients 6 months of age and older 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 less than 6 months of age.

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?

Adults 18 years of age and older:

EMEND 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.

Children 6 months to 17 years of age:

EMEND for injection will be given to your child by intravenous (IV) infusion into a large vein through a type of IV line called a central venous catheter, about 1 hour to 1 ½ hours before the start of their chemotherapy treatment. Depending on the chemotherapy treatment, there are 2 ways that EMEND for injection may be given:

- 1. EMEND for injection is given on Day 1 only (single day of chemotherapy).
- 2. EMEND for injection is given on Days 1, 2, and 3 (single or multiple days of chemotherapy).
 - Your child may receive capsules of EMEND or an oral suspension of EMEND instead of EMEND for injection on Days 2 and 3. If your child will receive either of these, see the Patient Information for EMEND capsules or EMEND for oral suspension for further information.

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, trouble breathing or swallowing, dizziness, a rapid or weak heartbeat, or you feel faint 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.
- Infusion site reactions (ISR) at or near the infusion site have happened with EMEND 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 EMEND for injection include:

- tiredness
- diarrhealow 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

In children 6 months to 17 years of age, the most common side effects of EMEND for injection include:

- low red blood cell count
- low white blood cell count

- low blood platelet count
- low white blood cell count with a fever

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 <u>www.emend.com</u>.

What are the ingredients in EMEND for injection?

Active ingredient: fosaprepitant

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

Manufactured for: Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA

Manufactured by: Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Highway, Greenville, NC 27834, USA For patent information: <u>www.msd.com/research/patent</u>

The brands listed in the above sections "Who should not receive 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 LLC.

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

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