

## PART III: CONSUMER INFORMATION

**EMEND® IV**  
**fosaprepitant for injection**  
**(as fosaprepitant dimeglumine)**

This leaflet is part III of a three-part "Product Monograph" published when EMEND® IV was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EMEND® IV. Contact your physician or pharmacist if you have any questions about the drug.

Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.

Remember that your physician has prescribed this medicine only for you. Never give it to anyone else.

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

EMEND® IV, in combination with 5-HT<sub>3</sub> antagonists and dexamethasone, is indicated for the prevention of nausea and vomiting associated with your cancer chemotherapy treatment.

#### **What it does:**

EMEND® IV is a member of a class of medicines called neurokinin 1 (NK<sub>1</sub>) receptor antagonists. Fosaprepitant when administered intravenously is rapidly converted to aprepitant. Aprepitant works by blocking neurokinin, a substance in the brain that causes nausea and vomiting.

#### **When it should not be used:**

Do not take EMEND® IV if you are allergic to fosaprepitant dimeglumine, aprepitant or any of the other ingredients of EMEND® IV.

Do not take EMEND® IV with pimozide, terfenadine, astemizole, or cisapride. Taking EMEND® IV with these medications could result in **serious or life-threatening problems**.

#### **What the medicinal ingredient is:**

Fosaprepitant dimeglumine

#### **What the important non-medicinal ingredients are:**

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

#### **What dosage forms it comes in:**

Powder for injection. Each vial contains 150 mg of fosaprepitant.

### WARNINGS AND PRECAUTIONS

#### Serious Warnings and Precautions

Drug interactions may occur with:

- Medicines that are likely to be broken down mainly by the liver. This may increase the levels of the medication in your blood.
- Warfarin. It may affect your blood test results.
- Hormonal contraception (birth control medicines). It may reduce the effectiveness of the birth control you are taking. Discuss with your physician regarding use of an alternate or backup method of birth control during and for 1 month after the last dose of EMEND® IV.

Possible serious side effects:

- Severe allergic (hypersensitivity) reactions during or soon after infusion. Signs include swelling (face, eyes, lips, tongue, throat and skin), rash, itching, redness of the face and skin, difficulty in breathing and swallowing, and serious drop in blood pressure.

BEFORE you use EMEND® IV talk to your physician or pharmacist if you:

- have any past or present medical problems
- have liver problems
- have any allergies
- drive a car or operate machinery
- are pregnant or plan to become pregnant
- are breast-feeding or plan to breast-feed

#### **Use in children**

EMEND® IV should not be given to children under 18 years of age.

#### **Use in the elderly**

No dosage adjustment is necessary.

### INTERACTIONS WITH THIS MEDICATION

Tell your physician about all medicines that you are taking or plan to take, even those you can get without a prescription or herbal products.

Your physician may check that your medicines are working properly together if you are taking other medicines such as:

- anti-anxiety drugs (such as alprazolam, midazolam)
- birth control medicines (which may not work as well)
- ketoconazole (an antifungal)
- rifampin (an antibiotic)
- paroxetine (a medicine used to treat a certain type of depression)
- diltiazem (a medicine used to treat high blood pressure)
- dexamethasone, methylprednisolone (steroid medicines used for a variety of conditions)
- warfarin (a blood thinner)

- tolbutamide (a medicine used to treat diabetes)
- phenytoin (a medicine used to treat seizures)
- some chemotherapy medications such as ifosfamide

### PROPER USE OF THIS MEDICATION

EMEND<sup>®</sup> IV may be taken with or without food.

#### Usual dose:

EMEND<sup>®</sup> IV 150 mg given on Day 1 only.

- Day of chemotherapy: EMEND<sup>®</sup> IV 150 mg will be given to you intravenously approximately 30 minutes before you start your chemotherapy treatment.

#### Overdose:

In case of a drug overdose, contact a health care practitioner, hospital emergency department or Regional Poison Control Centre, immediately.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all prescription drugs, EMEND<sup>®</sup> IV may cause side effects. Just because side effects have occurred in other patients does not mean you will get them. If you experience any side effects that bother you, please contact your doctor or pharmacist.

Side effects include:

- low white blood cell counts
- diarrhea
- stomach pain
- constipation
- upset stomach
- nausea
- vomiting
- fatigue
- dizziness
- weakness
- loss of appetite
- joint pain
- taste disturbance
- headache
- urinary tract infection
- dehydration
- pain and/or tingling in the limbs
- anxiety
- nose bleeds
- hiccups
- low red blood cell counts
- chest pain
- shortness of breath
- sores in the mouth

Infusion site reactions (ISR) at or near the infusion site have happened with EMEND<sup>®</sup> IV.

Most severe ISR have happened with a certain type of chemotherapy medicine that can burn or blister your skin with side effects, including pain, swelling, redness and hardening at the site of infusion. Death of skin tissue has happened in some people getting this type of chemotherapy medicine. Tell your healthcare provider right away if you get any infusion site side effects.

Side effects seen with EMEND<sup>®</sup> capsules may also be seen with EMEND<sup>®</sup> IV.

- upset stomach and pain
- trouble sleeping (insomnia)
- hair loss (alopecia)
- fever
- ringing in the ears
- slow heart rate
- ulcers
- disorientation

Ask your physician or pharmacist for more information. Both have a more complete list of side effects. Tell your physician or pharmacist promptly about these or any other unusual symptoms.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptoms / Effects		Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
		Only if severe	In all cases	
Uncommon	Allergic reactions, which may be sudden and/or serious, and may include: swelling (face, eyes, lips, tongue, throat and skin), rash, itching, redness of the face/skin, difficulty in breathing/ swallowing, and serious decrease of blood pressure.		✓	
Uncommon	Stevens-Johnson syndrome/toxic epidermal necrolysis (severe skin reactions, blistering)		✓	
Uncommon	Urticaria (severe rash, itching, swelling of the hands and feet)		✓	

*This is not a complete list of side effects. For any unexpected effects while taking EMEND® IV, contact your physician or pharmacist.*

**HOW TO STORE IT**

Vials: Sterile powder for intravenous use. Store at 2–8°C.

**Keep EMEND® IV and all medicines safely away from children.**

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON K1A 0K9
 Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

**If you want more information about EMEND® IV or EMEND® capsules:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the [Health Canada website](http://www.healthcanada.gc.ca) or Merck Canada website [www.merck.ca](http://www.merck.ca) or by calling Merck Canada at 1-800-567-2594

To report an adverse event related to EMEND® IV, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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