

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 were 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-HT₃ 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 (NK₁) 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 with:

- Medicines that are likely to be broken down mainly by the liver
- Warfarin
- Hormonal contraception (birth control medicines)

Possible serious side effects:

- Severe allergic (hypersensitivity) reactions during infusion

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

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

Following the infusion of EMEND® IV, the early concentration of aprepitant in the blood is double that of an EMEND® capsule (125 mg); therefore, a possible risk for increased side effects cannot be ruled out.

PROPER USE OF THIS MEDICATION

EMEND® IV may be taken with or without food.

Usual dose:

EMEND® IV 150 mg given on Day 1 only.

- Day of chemotherapy: EMEND® 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

Any medicine may have unintended or undesirable effects, so-called side effects.

Like all prescription drugs, EMEND® IV may cause side effects. The most common side effects included diarrhea, stomach pain, upset stomach, vomiting, dizziness, hiccups, fatigue, weakness, constipation, headache, and loss of appetite.

Infusion-site reactions included pain, hardening, swelling of a vein caused by a blood clot, redness, and/or itching at the infusion site.

Other side effects may also occur rarely, which include: anxiousness, fever with increased risk of infection, dry mouth, conjunctivitis (eye discharge and itching), excessive sweating, flushing, painful burning urination, muscle cramp or pain, taste disturbance, high blood pressure, ringing in the ear (tinnitus) and low blood pressure.

Allergic reactions, which may be sudden and/or serious, and may include hives, rash, itching, redness of the face/skin, and cause difficulty in breathing or swallowing.

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/Angioedema (swelling of the face, eyes, lips, tongue, throat, difficulty in breathing or swallowing)		√	
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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Also, you can report any suspected adverse reactions associated with the use of health products to Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-800-369-3090, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire–Dorval, QC H9R 4P8

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc.

at: 1-800-567-2594

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