

EMEND® IV

Fosaprepitant dimeglumine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EMEND IV. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using EMEND IV against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EMEND IV is used for

Chemotherapy Induced Nausea and Vomiting

EMEND IV, in combination with other medicines, is used to prevent

- nausea (feeling sick) and vomiting associated with cancer chemotherapy.

EMEND IV belongs to a group of medicines called neurokinin 1 (NK1) receptor antagonists. It works by blocking the actions of substances in your brain, called substance P neurokinins, that cause nausea and vomiting.

Your doctor may have prescribed EMEND IV for another reason. Ask your doctor if you have any questions about why EMEND IV has been prescribed for you.

The safety and effectiveness of EMEND IV in children and teenagers under the age of 18 years have not been established.

EMEND IV is not addictive.

Before you are given EMEND IV

When you must not be given it

Do not use EMEND IV if you have an allergy to EMEND IV, aprepitant or any of the ingredients listed at the end of this leaflet.

Do not use EMEND IV if you are taking:

- cisapride, used to treat stomach reflux
- pimozone, used to treat psychotic conditions
- terfenadine (Teldane®) and astemizole (Hismanal®), antihistamines used for allergic conditions, including hayfever # not available in Australia
- St John's Wort - a herb used to treat depression

Using EMEND IV with these medicines may cause serious or life-threatening reactions.

Do not use EMEND IV if you are breast-feeding or plan to breast-feed.

It is not known if EMEND IV passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not be given EMEND IV.

Do not use EMEND IV if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**
If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using EMEND IV, talk to your doctor.

Before you are given it

Tell your doctor if:

1. **you have or have had any medical conditions**
2. **you are pregnant or intend to become pregnant**
EMEND IV has not been studied in pregnant women. EMEND IV should be used during pregnancy only if clearly needed.
3. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you are given any EMEND IV.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with EMEND IV. These include:

- cisapride, used to treat stomach reflux
- pimozone, used to treat psychotic conditions
- terfenadine (Teldane®) and astemizole (Hismanal®), antihistamines used for allergic conditions, including hayfever # not available in Australia
- St John's Wort - a herb used to treat depression

Using EMEND IV with these medicines may cause serious or life-threatening reactions.

Some medicines and EMEND IV may interfere with each other. These include:

- warfarin, used to prevent blood clots. Your doctor may order additional blood tests to check the effect of warfarin after you have been given EMEND IV.
- rifampicin, an antibiotic used to treat tuberculosis and other infections
- ketoconazole, used to treat fungal infections
- oral contraceptive pills (also known as the pill). Alternative or "back-up" measures of contraception should be used during treatment with EMEND IV and for one month following the last dose of EMEND IV
- paroxetine, used to treat depression, and obsessive compulsive and panic disorders
- diltiazem, used to treat angina and high blood pressure
- midazolam, triazolam, or alprazolam, used as sedatives or to treat anxiety or panic disorder
- dexamethasone or methylprednisolone, steroid medicines used for a variety of conditions
- certain cancer chemotherapy agents, including etoposide, vinorelbine, paclitaxel
- tolbutamide, used to treat diabetes
- phenytoin, used to treat epilepsy

These medicines may be affected by EMEND IV or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using EMEND IV.

How EMEND IV is given

How much to be given

EMEND IV is to be given intravenously by your doctor and it contains 150 mg of fosaprepitant as the active ingredient.

EMEND IV must only be administered by your doctor or nurse.

Day 1 (Day of chemotherapy) -

EMEND IV 150 mg may be given to you as an infusion over 20-30 minutes approximately 30 minutes before you start your chemotherapy treatment.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How long to use it

Chemotherapy Induced Nausea and Vomiting

EMEND IV 150 mg is given only on the day of chemotherapy.

While you are using EMEND IV

Things you must do

- **Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with EMEND IV and for one month following the last dose of EMEND IV**
This is because oral contraceptive pills may not work as well when using EMEND IV.

If you become pregnant while using EMEND IV, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using EMEND IV.

Things to be careful of

Be careful driving or operating machinery until you know how EMEND IV affects you.

EMEND IV generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many medicines, it may cause certain side effects in some people, including tiredness and dizziness. Make sure you know how you react to EMEND IV before you drive a car or operate machinery.

Things that may be helpful to manage your chemotherapy induced nausea and vomiting

Small, frequent meals or eating a snack before your chemotherapy treatment may help you to tolerate it better.

Talk to your doctor, pharmacist or nurse for more information.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given EMEND IV.

EMEND IV helps most people with nausea and vomiting associated with cancer chemotherapy, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- tiredness
- generally feeling unwell
- muscle weakness
- headache, dizziness
- constipation, diarrhoea
- indigestion, heartburn, loss of appetite
- gas from the stomach or bowel, wind
- hiccups/hiccoughs
- vomiting
- disorientation
- chills
- hot flushes
- bloating
- pain on urination
- changes to your walking pattern
- acne
- injection site pain
- hardening at the injection site
- redness and/or itching at infusion site

Most of these are the more common side effects. For the most part these have been mild.

Tell your doctor immediately if you notice the following:

- slow, fast or irregular heart beat
- severe upper stomach pain
- symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering
- signs of anaemia such as, being short of breath when exercising, looking pale
- frequent signs of infections such as fever, severe chills, sore throat or mouth ulcers
- Infusion site reactions (ISR) at or near the infusion site. These reactions have happened with EMEND IV. 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.

These may be serious side effects. You may need urgent medical attention. These side effects are rare.

If any of the following happen, tell your doctor immediately or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives or nettlerash

- severe skin reactions, including the inside of the nose or mouth
- serious decrease of blood pressure

These may be serious side effects. If you have them, you may be having a serious allergic reaction to EMEND IV. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using EMEND IV

Storage

EMEND IV will be stored in the pharmacy or on the ward.

It is kept in a refrigerator where the temperature stays between 2-8°C.

Product description

What it looks like

EMEND IV comes as a white to off-white powder in a glass vial.

Ingredients

Active ingredient:

Each vial of EMEND IV 150 mg contains fosaprepitant dimeglumine equivalent to 150 mg of fosaprepitant free acid.

Inactive ingredients:

- disodium edetate
- polysorbate 80
- lactose
- sodium hydroxide or hydrochloric acid

EMEND IV does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited

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