

# EMEND IV<sup>®</sup>

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given EMEND IV?

EMEND IV contains the active ingredient fosaprepitant dimeglumine. EMEND IV is used in combination with other medicines to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy.

For more information, see Section [1. Why am I being given EMEND IV?](#) in the full CMI.

### 2. What should I know before I am given EMEND IV?

Do not use if you have ever had an allergic reaction to EMEND IV or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given EMEND IV?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with EMEND IV and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How am I given EMEND IV?

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

More instructions can be found in Section [4. How am I given EMEND IV?](#) in the full CMI.

### 5. What should I know while being given EMEND IV?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• 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</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>

For more information, see Section [5. What should I know while being given EMEND IV?](#) in the full CMI.

### 6. Are there any side effects?

Like all medicines, Emend IV can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using EMEND IV.

When you get Emend IV, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# EMEND IV<sup>®</sup>

Active ingredient: *fosaprepitant dimeglumine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using EMEND IV. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EMEND IV.**

**Where to find information in this leaflet:**

- [1. Why am I being given EMEND IV?](#)
- [2. What should I know before I am given EMEND IV?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given EMEND IV?](#)
- [5. What should I know while being given EMEND IV?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given EMEND IV?

EMEND IV<sup>®</sup> contains the active ingredient fosaprepitant dimeglumine.

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.

**EMEND IV is used in combination with other medicines to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy.**

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.

### 2. What should I know before I am given EMEND IV?

#### Warnings

**Do not use EMEND IV if:**

- you are allergic to fosaprepitant dimeglumine, aprepitant or any of the ingredients listed at the end of this leaflet.**

Always check the ingredients to make sure you can use this medicine.

- You are taking the following medicines:**
  - cisapride, used to treat stomach reflux
  - pimozide, used to treat psychotic conditions
  - terfenadine and astemizole, antihistamines used for allergic conditions, including hayfever
  - St John's Wort - a herb used to treat depression

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

- 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.

- 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.

**Check with your doctor if you:**

- have or have had any other medical conditions**
- 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

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**Check with your doctor if 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.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

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.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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
- pimozide**, used to treat psychotic conditions
- terfenadine and astemizole**, antihistamines used for allergic conditions, including hayfever
- 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 may interfere with EMEND IV and affect how it works. 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EMEND IV.**

#### 4. How am I given EMEND IV?

##### 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 150mg 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

##### If you use too much EMEND IV

If you think that you have been given too much EMEND IV, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while being given EMEND IV?

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

##### Call your doctor straight away if you:

- become pregnant while using EMEND IV

##### Managing 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

##### Driving or using machines

##### 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.

##### Looking after your medicine

- 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.

##### Keep it where young children cannot reach it.

##### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

##### Less serious side effects

Less serious side effects	What to do
Tell your doctor if you notice or have any of the following and they worry you:	<b>Speak to your doctor if you have any of</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>tiredness</li> <li>generally feeling unwell</li> <li>muscle weakness</li> <li>headache, dizziness</li> <li>constipation, diarrhoea</li> <li>indigestion, heartburn, loss of appetite</li> <li>gas from the stomach or bowel, wind</li> <li>hiccups/hiccoughs</li> <li>vomiting</li> <li>disorientation</li> <li>chills</li> <li>hot flushes</li> <li>bloating</li> <li>pain on urination</li> <li>changes to your walking pattern</li> <li>acne</li> <li>injection site pain</li> <li>hardening at the injection site</li> <li>redness and/or itching at infusion site</li> </ul> <p>Most of these are the more common side effects. For the most part these have been mild.</p>	<p><b>these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<p>Tell your doctor immediately if you notice the following:</p> <ul style="list-style-type: none"> <li>slow, fast or irregular heartbeat</li> <li>severe upper stomach pain</li> <li>symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering</li> <li>signs of anaemia such as, being short of breath when exercising, looking pale</li> <li>frequent signs of infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>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.</li> </ul> <p><b>If any of the following happen, tell your doctor immediately or go to accident and emergency at your nearest hospital:</b></p> <ul style="list-style-type: none"> <li>swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>pinkish, itchy swellings on the skin, also called hives or nettle rash</li> <li>severe skin reactions, including the inside of the nose or mouth</li> </ul> <p>serious decrease of blood pressure</p> <p>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.</p>	

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What EMEND IV contains

<b>Active ingredient (main ingredient)</b>	fosaprepitant dimeglumine
<b>Other ingredients (inactive ingredients)</b>	disodium edetate polysorbate 80 lactose sodium hydroxide or hydrochloric acid

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

**Do not take this medicine if you are allergic to any of these ingredients.**

#### What EMEND IV looks like

EMEND IV 150 mg comes as a white to off-white powder in a glass vial (AUST R 167061).

#### Who distributes EMEND IV

Merck Sharp & Dohme (Australia) Pty Limited  
Level 1, Building A, 26 Talavera Rd  
MACQUARIE PARK NSW 2113

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