

EMEND®

Aprepitant

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EMEND. 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 taking EMEND against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What EMEND is used for

Chemotherapy Induced Nausea and Vomiting

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

Post-Operative Nausea and Vomiting

EMEND is used to prevent nausea (feeling sick) and vomiting which can occur after surgery.

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

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

EMEND is not addictive.

Before you take EMEND

When you must not take it

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

Do not take EMEND if you are taking:

- cisapride, used to treat stomach reflux
 - pimozide, used to treat psychotic conditions
 - terfenadine (Teldane*) and astemizole (Hismanal*), antihistamines used for allergic conditions, including hayfever
- * not available in Australia
- St Johns Wort - a herb used to treat depression

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

Do not take EMEND if you have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase insufficiency.

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

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

Do not take EMEND if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

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

Before you take it

Tell your doctor if:

1. **you have or have had any medical conditions**
2. **you are pregnant or intend to become pregnant**

EMEND has not been studied in pregnant women. EMEND 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 the doctor before you take any EMEND.

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. These include:

- cisapride, used to treat stomach reflux
- pimozide, 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

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

Some medicines and EMEND 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 taken EMEND.
- 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 and for one month following the last dose of EMEND
- 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 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 taking EMEND.

How to take EMEND

How much to take

Take EMEND only when prescribed by your doctor.

Chemotherapy Induced Nausea and Vomiting

EMEND may be given to you in one of two ways:

1. EMEND 1-Day Regimen

Day 1 (day of chemotherapy):

One 165 mg capsule of EMEND will be given to you to take by mouth 1 hour before you start your chemotherapy treatment on Day 1 only.

OR

2. EMEND 3-Day Regimen

Day 1 (day of chemotherapy):

EMEND 125 mg will be given to you by mouth 1 hour before you start your chemotherapy treatment on Day 1.

Day 2 and Day 3 (the two days after chemotherapy):

Take one 80 mg capsule of EMEND each morning for the 2 days following your chemotherapy treatment.

Post-Operative Nausea and Vomiting

The recommended dose of EMEND to prevent nausea and vomiting caused by surgery is one 40 mg

capsule within 3 hours before your surgery.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How to take it

Chemotherapy Induced Nausea and Vomiting

Swallow each capsule of EMEND whole with a glass of water.

It does not matter if you take EMEND before, with or after food. However, if you are taking the 165 mg capsule, take it either without food or with a light meal.

Post-Operative Nausea and Vomiting

Your doctor will give you one 40 mg capsule of EMEND 3 hours before your surgery.

EMEND can be taken with or without food. Follow your doctor's instructions about eating or drinking before surgery.

How long to take it

Chemotherapy Induced Nausea and Vomiting

EMEND may be given in one of two ways. EMEND 1-Day regimen is a 165 mg capsule given only on the day of chemotherapy treatment.

EMEND 3-Day regimen is usually taken for 3 days.

Post-Operative Nausea and Vomiting

EMEND is given as 1 dose before your surgery.

If you are not sure how long to take EMEND, talk to your doctor.

If you forget to take it

If you forget to take your capsules, contact your doctor for instructions.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much EMEND. Do this even if there are no signs of discomfort or poisoning.

While you are using EMEND

Things you must do

Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with EMEND and for one month following the last dose of EMEND.

This is because oral contraceptive pills may not work as well when taking EMEND.

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

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

Things you must not do

Do not give EMEND to anyone else, even if they have the same condition as you.

Things to be careful of

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

EMEND 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 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.

Things that may be helpful to manage your nausea and vomiting caused by your surgery

Talk to your doctor about measures to manage your nausea and vomiting after surgery.

Side Effects

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

EMEND 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

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

Tell your doctor immediately if you notice any of 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

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

These may be serious side effects. If you have them, you may be having a serious allergic reaction to EMEND. 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

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take them out of the blister pack, they may not keep well.

Keep EMEND in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking EMEND, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

EMEND comes in four types of capsules:

- EMEND 165 mg - white and light blue coloured, with "466" and "165 mg" printed in black ink on the capsule
- EMEND 125 mg - white and pink coloured, with "462" and "125 mg" printed in black ink on the capsule

- EMEND 80 mg - white coloured with "461" and "80 mg" printed in black ink on the capsule.
- EMEND 40 mg * - white and mustard coloured, with "464" and "40 mg" printed in black on the capsule

The capsules come in:

- A box of EMEND 165 mg containing one capsule
- A box of EMEND 165 mg containing six capsules *
- A 3-day box containing one 125 mg capsule and two 80 mg capsules
- A box of EMEND 125 mg containing one capsule. *
- A box of EMEND 80 mg containing one capsule *
- A box of EMEND 80 mg containing two capsules.
* not currently available in Australia

Ingredients

Active ingredient:

- EMEND 165 mg - 165 mg aprepitant per capsule
- EMEND 125 mg - 125 mg aprepitant per capsule
- EMEND 80 mg - 80 mg aprepitant per capsule
- EMEND 40 mg - 40 mg aprepitant per capsule

Inactive ingredients:

- sucrose
- microcrystalline cellulose
- hydroxypropyl cellulose
- sodium lauryl sulphate

Capsule shell ingredients:

- gelatin
- titanium dioxide CI77891
- iron oxide red CI 77491 (125 mg capsules)
- iron oxide yellow CI 77492 (40 mg and 125 mg capsules)
- iron oxide black CI 77499
- indigo carmine (165 mg capsule)

- sodium lauryl sulphate
- colloidal silicon dioxide

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

Supplier

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A

26 Talavera Road

Macquarie Park NSW 2113

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Australian Register Numbers:

165 mg - AUST R 182320

125 mg/80mg 3 day pack AUST R 95775

125 mg - AUST R 95774

80 mg - AUST R 95773

40 mg - AUST R 123271