Package leaflet: Information for the user

EMEND® 125 mg hard capsules
EMEND® 80 mg hard capsules
aprepitant

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you are the parent of a child taking EMEND, please read this information carefully.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor, pharmacist, or nurse.
- This medicine has been prescribed for you or the child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If you or the child gets any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What EMEND is and what it is used for

EMEND contains the active substance aprepitant and belongs to a group of medicines called "neurokinin 1 (NK_1) receptor antagonists". The brain has a specific area that controls nausea and vomiting. EMEND works by blocking signals to that area, thereby reducing nausea and vomiting. EMEND capsules are used in adults and adolescents from the age of 12 years **in combination with other medicines** to prevent nausea and vomiting caused by chemotherapy (cancer treatment) that are strong and moderate triggers of nausea and vomiting (such as cisplatin, cyclophosphamide, doxorubicin or epirubicin).

2. What you need to know before you take or give EMEND

Do not take EMEND:
- if you or the child is allergic to aprepitant or any of the other ingredients of this medicine (listed in section 6).

- with medicines containing pimozide (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems). Tell the doctor if you or the child is taking these medicines since the treatment must be modified before you or the child start taking EMEND.

Warnings and precautions
Talk to the doctor, pharmacist, or nurse before you take EMEND or give this medicine to the child.

Before treatment with EMEND, tell the doctor if you or the child have liver disease because the liver is important in breaking down the medicine in the body. The doctor may therefore have to monitor the condition of your or the child's liver.

Children and adolescents
Do not give EMEND 80 mg and 125 mg capsules to children under 12 years of age, because the 80 mg and 125 mg capsules have not been studied in this population.

Other medicines and EMEND
EMEND can affect other medicines both during and after treatment with EMEND. There are some medicines that should not be taken with EMEND (such as pimozide, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also 'Do not take EMEND').

The effects of EMEND or other medicines might be influenced if you or the child take EMEND together with other medicines including those listed below. Please talk to the doctor or pharmacist if you or the child is taking any of the following medicines:

- birth control medicines which can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones may not work adequately when taken together with EMEND. Another or additional non-hormonal form of birth control should be used during treatment with EMEND and for up to 2 months after using EMEND,
- cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
- alfentanil, fentanyl (used to treat pain),
- quinidine (used to treat an irregular heart beat),
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer),
- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- warfarin, acenocoumarol (blood thinners; blood tests may be required),
- rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep),
- St. John's Wort (an herbal preparation used to treat depression),
- protease inhibitors (used to treat HIV infections)
- ketoconazole except shampoo (used to treat Cushing's syndrome - when the body produces an excess of cortisol),
- itraconazole, voriconazole, posaconazole (antifungals),
- nefazodone (used to treat depression),
- corticosteroids (such as dexamethasone and methylprednisolone),
- anti-anxiety medicines (such as alprazolam),
- tolbutamide (a medicine used to treat diabetes).

Tell the doctor or pharmacist if you or the child are taking, have recently taken, or might take any other medicines.

Pregnancy and breast-feeding
This medicine should not be used during pregnancy unless clearly necessary. If you or the child are pregnant or breast-feeding, may be pregnant or are planning to have a baby, ask the doctor for advice before taking this medicine.

For information regarding birth control, see 'Other medicines and EMEND'.

It is not known whether EMEND is excreted in human milk; therefore, breast-feeding is not recommended during treatment with this medicine. It is important to tell the doctor if you or the child are breast-feeding or are planning to breast-feed before taking this medicine.

Driving and using machines
It should be taken into account that some people feel dizzy and sleepy after taking EMEND. If you or the child feels dizzy or sleepy, avoid driving, riding a bicycle or using machines or tools after taking this medicine (see 'Possible side effects').

EMEND contains sucrose
EMEND capsules contain sucrose. If you or the child have been told by your doctor that you or the child have an intolerance to some sugars, contact the doctor before taking this medicine.

3. How to take EMEND

Always take this medicine or give this medicine to the child exactly as the doctor, pharmacist or nurse has told you. You should check with the doctor, pharmacist or nurse if you are not sure. Always take EMEND together with other medicines, to prevent nausea and vomiting. After treatment with EMEND, the doctor may ask you or the child to continue taking other medicines including a corticosteroid (such as dexamethasone) and a '$5HT_3$ antagonist' (such as ondansetron) for preventing nausea and vomiting. Check with the doctor, pharmacist or nurse if you are not sure.

The recommended oral dose of EMEND is
Day 1:
- one 125 mg capsule 1 hour before you start your chemotherapy session

and

Days 2 and 3:
- one 80 mg capsule each day
- If no chemotherapy is given, take EMEND in the morning.
- If chemotherapy is given, take EMEND 1 hour before you start your chemotherapy session.

EMEND can be taken with or without food.

Swallow the capsule whole with some liquid.

If you take more EMEND than you should
Do not take more capsules than the doctor recommends. If you or the child has taken too many capsules, contact your doctor immediately.

If you forget to take EMEND
If you or the child has missed a dose, contact your doctor for advice.

If you have any further questions on the use of this medicine, ask the doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking EMEND and see a doctor immediately if you or the child notice any of the following side effects, which may be serious, and for which you or the child may need urgent medical treatment:
- Hives, rash, itching, difficulty breathing or swallowing (frequency not known, cannot be estimated from the available data); these are signs of an allergic reaction.

Other side effects that have been reported are listed below.

Common side effects (may affect up to 1 in 10 people) are:
- constipation, indigestion,
- headache,
- tiredness,
- loss of appetite,
- hiccups,

- increased amount of liver enzymes in your blood.

Uncommon side effects (may affect up to 1 in 100 people) are:
- dizziness, sleepiness,
- acne, rash,
- anxiousness,
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind,
- increased painful or burning urination,
- weakness, generally feeling unwell,
- hot flush/reddening of the face or skin,
- fast or irregular heartbeats,
- fever with increased risk of infection, lowering of red blood cells.

Rare side effects (may affect up to1 in 1,000 people) are:
- difficulty thinking, lack of energy, taste disturbance,
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin, itching rash, Stevens-Johnson syndrome/toxic epidermal necrolysis (rare severe skin reaction),
- euphoria (feeling of extreme happiness), disorientation,
- bacterial infection, fungal infection,
- severe constipation, stomach ulcer, inflammation of the small intestine and colon, sores in mouth, bloating,
- frequent urination, passing more urine than normal, presence of sugar or blood in urine,
- chest discomfort, swelling, change in the manner of walking,
- cough, mucus in back of throat, throat irritation, sneezing, sore throat,
- eye discharge and itching,
- ringing in the ear,
- muscle spasms, muscle weakness,
- excessive thirst,
- slow heartbeat, heart and blood vessel disease,
- lowering of white blood cells, low sodium levels in the blood, weight loss.

Reporting of side effects
If you or the child gets any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie
Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. How to store EMEND

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not remove the capsule from its blister until you are ready to take it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What EMEND contains

- The active substance is aprepitant. Each 125 mg hard capsule contains 125 mg of aprepitant. Each 80 mg hard capsule contains 80 mg of aprepitant.
- The other ingredients are: sucrose, microcrystalline cellulose (E 460), hydroxypropylcellulose (E 463), sodium laurilsulfate, gelatin, titanium dioxide (E 171), shellac, potassium hydroxide, and black iron oxide (E 172); the 125 mg hard capsule also contains red iron oxide (E 172) and yellow iron oxide (E 172).

What EMEND looks like and contents of the pack

The 125 mg hard capsule is opaque with a white body and pink cap with "462" and "125 mg" printed radially in black ink on the body.
The 80 mg hard capsule is opaque with a white cap and body with "461" and "80 mg" printed radially in black ink on the body.

EMEND 125 mg and 80 mg hard capsules are supplied in the following pack size:

- 3-day treatment pack containing one 125 mg capsule and two 80 mg capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Merck Sharp & Dohme B.V.
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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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