

## 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.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What EMEND is and what it is used for
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## **1. WHAT EMEND IS AND WHAT IT IS USED FOR**

EMEND is used **in combination with other medicines** to prevent nausea and vomiting caused by chemotherapy (cancer treatment).

## **2. BEFORE YOU TAKE EMEND**

#### **Do not take EMEND**

- If you are allergic (hypersensitive) to aprepitant or any of the other ingredients of EMEND.
- 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 your doctor if you are taking these medicines since your treatment must be modified before you start taking EMEND.

#### **Take special care with EMEND**

- if you have liver disease

EMEND is not for use in children and adolescents under 18 years.

#### **Using other medicines**

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 dosage adjustment (see also Do not take EMEND).

EMEND should be used with caution when taken with other medicines.

The effects of EMEND or other medicines might be influenced if you take EMEND together with other medicines including those listed below.

- cyclosporine, tacrolimus, sirolimus, and everolimus (immunosuppressants),
- alfentanil, and fentanyl (used to treat pain),

- quinidine (used to treat an irregular heart beat),
- irinotecan (medicine used to treat cancer),
- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- warfarin (a blood thinner; blood tests may be required),
- birth control medicines (which may not work as well; another or additional form of birth control should be used for up to 2 months after using EMEND),
- rifampin, clarithromycin, telithromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),
- midazolam, triazolam, and 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 itraconazole, voriconazole, and posaconazole (antifungals),
- nefazodone (used to treat depression),
- corticosteroids (such as dexamethasone and methylprednisolone),
- anti-anxiety drugs (such as alprazolam), and
- tolbutamide (a medicine used to treat diabetes)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### **Taking EMEND with food and drink**

EMEND can be taken with or without food.

#### **Pregnancy and breast-feeding**

You should not use EMEND during pregnancy unless clearly necessary. It is important that you tell your doctor if you are pregnant or are planning to become pregnant before taking EMEND.

Birth control medicines (these can include birth control pills, skin patches, implants, and certain Intrauterine devices [IUDs] that release hormones) may not work adequately; another or additional form of contraception should be used during treatment with EMEND and for up to 2 months after using EMEND.

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

#### **Driving and using machines**

It should be taken into account that some people feel dizzy and sleepy after taking EMEND. If you feel dizzy or sleepy, you should avoid driving or operating machines after taking EMEND. (See POSSIBLE SIDE EFFECTS).

#### **Important information about some of the ingredients of EMEND**

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

### 3. HOW TO TAKE EMEND

Always take EMEND exactly as your doctor has instructed you.

**The recommended oral dose of EMEND is**

one 125 mg capsule 1 hour before you start your chemotherapy treatment on Day 1

**and**

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

Your doctor may substitute fosaprepitant 115 mg (which is converted to aprepitant in your body) for oral EMEND (125 mg) on Day 1 only of your treatment. Fosaprepitant is given via an intravenous infusion (a drip), 30 minutes prior to chemotherapy. You will still need to take one 80 mg capsule by mouth of EMEND each morning for the 2 days following your chemotherapy treatment.

EMEND should be swallowed whole with some liquid.

**If you take more EMEND than you should**

Do not take more capsules than the doctor recommends. If you do take too many capsules, contact your doctor immediately.

**If you forget to take EMEND**

If you have missed a dose, contact your doctor for advice.

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

### 4. POSSIBLE SIDE EFFECTS

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

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data).

Common side effects are:

- burping, constipation, diarrhoea, indigestion,
- dizziness, headache,
- weakness, tiredness,
- loss of appetite,
- hiccups,
- increased liver blood tests.

Uncommon side effects are:

- abnormal dreaming, difficulty thinking, lack of energy, sleepiness,
- acne, oily skin, rash, itching, sensitivity of the skin to sun, sores on skin, excessive sweating,
- anxiousness, euphoria (feeling of extreme happiness), disorientation
- bacterial infection, fungal infection,
- stomach ulcer, nausea, vomiting, heartburn, taste disturbance, stomach pain, bloating, severe constipation, dry mouth, inflammation of the small intestine and colon, passing wind, sores in mouth,
- presence of red blood cells in the urine, increased painful or burning urination, passing more urine than normal,

- chest discomfort, swelling, generally feeling unwell, chills, change in the manner of walking
- reddening of the face, hot flush,
- cough, mucus in back of throat, throat irritation, sneezing, sore throat,
- eye discharge and itching,
- ringing in the ear,
- muscle cramp or pain, muscle weakness,
- excessive thirst, weight gain or loss, high sugar levels in the blood,
- slow heartbeat, fast or irregular heart beats, heart and blood vessel disease,
- fever with increased risk of infection, lowering of red blood cells lowering of white blood cells, low sodium levels in the blood.

Single cases of the following have been reported:

- Stevens-Johnson syndrome (rare severe skin reaction),
- angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing),
- serious constipation, small bowel not working properly (sub-ileus),
- urticaria (hives).

Since the product has been on the market, the following side effects have been reported (frequency not known):

- Allergic reactions, which may be serious, and may include hives, rash and itching and cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking EMEND and call your doctor right away.

If any of the side effects gets serious, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE EMEND

Keep out of the reach and sight of children.

Do not use EMEND after the expiry date which is stated on the carton. 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER 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), hydroxypropyl cellulose (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). The capsule shell may also contain sodium laurilsulfate and silica colloidal anhydrous.

**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 sizes:

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

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>.