

<b>Product Name: EMEND 80 and 125 CAPSULES and COMBIPACK</b>	<b>Component: English Patient Information Leaflet</b> <b>Date approved: 10 June 2016</b>
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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### PROPRIETARY NAME AND DOSAGE FORM

EMEND® 80 Capsules

EMEND® 125 Capsules

EMEND® Combi Pack Capsules

### Read all of this leaflet carefully before you start taking EMEND

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- EMEND has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### 1. WHAT EMEND CONTAINS

EMEND (aprepitant MSD) is a capsule that contains either 125 mg, or 80 mg of aprepitant as the active ingredient.

In addition, EMEND contains the following inactive ingredients: Hydroxypropyl cellulose, microcrystalline cellulose, sodium lauryl sulphate, sucrose, gelatin capsule and black ink.

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## **2. WHAT EMEND IS USED FOR**

EMEND is a member of a class of medicines called neurokinin 1 (NK<sub>1</sub>) receptor antagonists that is used along with other medicines to prevent and control nausea (sick feeling in the back of throat and stomach) and vomiting (throwing up) caused by your cancer chemotherapy treatment.

Your doctor has prescribed EMEND for the prevention of nausea and vomiting associated with your cancer chemotherapy treatment.

## **3. BEFORE YOU TAKE EMEND**

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

- If you are hypersensitive (allergic) to aprepitant or any of the other ingredients of EMEND.

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

Tell your doctor about any of the following that apply to you:

- If you have or have had any past or present medical problems.
- If you have any allergies.
- If you are taking or plan to take any medicine, including those you can get without a prescription or herbal products.

### **Use in children**

EMEND has not been adequately studied in children. Therefore, EMEND should not be given to children.

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### **Use in the elderly**

No dosage adjustment is necessary for elderly patients.

### **Pregnancy and breastfeeding**

EMEND is not recommended during pregnancy and breastfeeding.

If you are taking EMEND you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

**Important information about some of the ingredients of EMEND:** If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking EMEND.

Contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

### **Driving and using machinery**

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 using machines after taking EMEND (see “**POSSIBLE SIDE EFFECTS**”).

### **Taking other medicines with EMEND**

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Do not take EMEND with pimozide, astemizole or cisapride. Taking EMEND with these medications could result in serious or life-threatening problems.

Your doctor may check that your medicines are working properly together if you are taking other medicines such as:

- anti-anxiety medicines (such as alprazolam)
- birth control medicines (which may not work as well)
- warfarin (a blood thinner)
- ketoconazole (an antifungal)
- rifampicin (an antibiotic)
- paroxetine (a medicine used to treat a certain type of depression)
- diltiazem (a medicine used to treat high blood pressure)
- tolbutamide (a medicine used to treat diabetes)
- phenytoin (a medicine used to treat seizures).

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

#### **4. HOW TO TAKE EMEND**

Always take EMEND exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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The recommended dose of EMEND is one 125 mg capsule by mouth 1 hour before you start your chemotherapy treatment and one 80 mg capsule each morning for the 2 days following your chemotherapy treatment.

EMEND may be taken with or without food.

Your doctor will tell you how long your treatment with EMEND will last. Do not stop treatment early. If you have the impression that the effect of EMEND is too strong or too weak, tell your doctor or pharmacist.

Do not share medicines prescribed for you with others.

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

If you take more than the prescribed dosage, contact your doctor immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forgot to take/missed a dose of EMEND:**

If you miss a dose, contact your physician for further instructions.

**5. POSSIBLE SIDE EFFECTS**

EMEND can have side effects.

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The most frequent side effects include hiccups, fatigue, constipation, headache, indigestion, increased liver enzymes and loss of appetite.

The following side effects have been reported with EMEND:

- 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.
- Severe skin reactions may occur.

Other side effects may also occur. Ask your doctor or pharmacist for more information. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

Not all side effects reported for EMEND are included in this leaflet. If your general health worsens or if you experience any untoward effects while taking EMEND, please consult your doctor, pharmacist or other healthcare professional for advice.

## **6. STORING AND DISPOSING OF EMEND**

Store at or below 25 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton.

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## **7. PRESENTATION OF EMEND**

EMEND 80 and 125 mg capsules are supplied in a carton containing 5 capsules individually packaged in single aluminium foil blisters. Each carton contains 5 blisters.

EMEND Combi Pack capsules are supplied as individually packed single aluminium foil blister packs as a combination containing one 125 mg capsule and two 80 mg capsules in a carton.

## **8. IDENTIFICATION OF EMEND**

EMEND 80 mg capsule: White, opaque hard gelatin capsule with 461 and 80 mg printed radially in black ink.

EMEND 125 mg capsule: Opaque, hard gelatin capsule with white body and pink cap with 462 and 125 mg printed radially in black ink.

## **9. REGISTRATION NUMBERS**

EMEND 80 Capsules: A38/5.7.2/0626

EMEND 125 Capsules: A38/5.7.2/0627

EMEND Combi Pack Capsules: A38/5.7.2/0625

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

MSD (Pty) Ltd

117 16<sup>th</sup> Road

Halfway House

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South Africa

Tel. No.: 011 655 8000

## **11. DATE OF PUBLICATION**

Date on the registration certificate: 23 September 2005

Date of the most recently revision as approved: 10 June 2016

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