

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS  
(PREPARATIONS) 1986**

This medicine can be sold under doctor's prescription only

**EMEND<sup>®</sup>  
80 mg  
Capsules**

Each capsule contains:  
Aprepitant 80 mg

**EMEND<sup>®</sup>  
125 mg  
Capsules**

Each capsule contains:  
Aprepitant 125 mg

For a list of inactive ingredients see section 6 "**FURTHER INFORMATION**". See also section 2.8 "**Important information about some of the ingredients of EMEND**".

**Read the entire leaflet carefully before you start taking this medicine.**

- This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or the pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
- This medicine is not intended for children and adolescents under 18 years of age.

## **1. WHAT EMEND IS INTENDED FOR?**

**EMEND** capsules are intended for use in adult patients, **in combination with other anti-emetic medicines**:

- To prevent acute and delayed nausea and vomiting caused by chemotherapy (cancer treatment) of highly emetogenic potential (strong trigger of nausea and vomiting).
- To prevent chemotherapy induced nausea and vomiting (CINV) that are caused by chemotherapy (cancer treatment) of moderate emetogenic potential (moderate trigger of nausea and vomiting).

**Therapeutic group:** **EMEND** is a neurokinin 1 (NK<sub>1</sub>) receptor antagonist.

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

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

- if you are hypersensitive (allergic) to aprepitant or any of the other ingredients of **EMEND** (for a list of inactive ingredients, see 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 your doctor if you are taking these medicines since your treatment must be modified before you start taking **EMEND**. Taking **EMEND** with these medications could result in **serious or life-threatening problems**.

### **2.2 Special warnings concerning use of EMEND**

**Before starting treatment with EMEND, tell your doctor if:**

- you have liver disease because your liver is important in breaking down the medicine in your body. Your doctor may therefore have to monitor the condition of your liver.

### **2.3 Children and adolescents**

**EMEND** is not approved for use in children.

### **2.4 Taking other medicines**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should tell the attending doctor or pharmacist.**

**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 section 2.1 “**Do not take EMEND**”).

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

Especially inform your doctor or pharmacist if you are taking:

- 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 (Hypericum - a 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).

## 2.5 Taking **EMEND** with food

**EMEND** can be taken with or without food.

## 2.6 Pregnancy, breast-feeding and fertility

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

For information regarding birth control, see section 2.4 “**Taking other medicines**”.

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 that you tell your doctor if you are breast-feeding or are planning to breast-feed before taking this medicine.

## 2.7 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 using machines or tools after taking this medicine (see section 4 “**SIDE EFFECTS**”).

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

**EMEND** contains sucrose

**EMEND** capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine (see also section 6 “**What EMEND contains?**”).

**EMEND contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

**3. HOW SHOULD YOU USE EMEND?**

Always take this medicine as instructed by the doctor. You should check with the doctor or pharmacist if you are not sure about the dosage and method of treatment.

The dosage and method of treatment will be determined by the doctor only.

Always take **EMEND** together with other medicines, to prevent nausea and vomiting. After your treatment with **EMEND**, your doctor will ask you to continue taking other medicines including a corticosteroid (such as dexamethasone) and a “5HT<sub>3</sub> antagonist” (such as ondansetron) for preventing nausea and vomiting.

Check with the doctor or pharmacist if you are not sure.

The usually recommended dose 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, in the morning.

**Do not exceed the recommended dose.**

**EMEND** can be taken with or without food.

Swallow the capsule whole with some liquid.

No information is available regarding opening and dispersing content of capsules.

**Examinations and monitoring**

Before starting treatment with **EMEND** tell your doctor if you have liver disease. Your doctor may have to monitor the condition of your liver.

**If you have accidentally taken a higher dose than you should**

Do not take more capsules than the doctor recommends.

If you have taken more capsules than the doctor recommends, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

**If you forget to take EMEND**

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

Complete the course of treatment as recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.**

While good nutrition is important for everyone, it is especially important for people on chemotherapy.

Small, frequent meals or eating a snack before your chemotherapy treatment may also help you tolerate it better.

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

#### **4. SIDE EFFECTS**

Like all medicines, **EMEND** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

**Stop taking EMEND and see a doctor immediately if you notice any of the following side effects, which may be serious, and for which you 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,
- fast or irregular heartbeats,
- fever with increased risk of infection, lowering of red blood cells.

**Rare side effects (may affect up to 1 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 adverse 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.

**If a side effect appears, if any of the side effects worsens or if you notice a side effect not mentioned in this leaflet, consult your doctor.**

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site ([www.health.gov.il](http://www.health.gov.il)) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il>.

## 5. HOW TO STORE EMEND?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store below 30°C. 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?

In addition to the active ingredient the medicine also contains inactive ingredients: Sucrose, Microcrystalline Cellulose Beads, Hydroxypropyl Cellulose SL, Micronized Sodium Lauryl Sulfate, Sodium Lauryl sulfate, gelatin, titanium dioxide (E 171), shellac, potassium hydroxide, black iron oxide (E 172); The 125 mg capsule also contains red iron oxide (E 172), yellow iron oxide (E 172).

**EMEND** contains sucrose (see also section 2.8, "**Important information about some of the ingredients of EMEND**").

**EMEND** 125 mg capsule contains 125 mg sucrose.

**EMEND** 80 mg capsule contains 80 mg sucrose.

### What EMEND looks like and contents of the pack

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

The 80 mg capsule is a gelatin capsule, opaque with a white cap and body with "461" and "80 mg" printed radially in black ink on the body.

Pack sizes: 3-day treatment pack containing one 125 mg capsule and two 80 mg capsules.

### Marketing authorization holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

### Manufacturer:

Merck Sharp & Dohme Corp., New-Jersey, USA.

Revised in December 2020.

### Drug registration no. listed in the official registry of the Ministry of Health:

**EMEND** 80 mg capsules: 135.08.31206

**EMEND** 125 mg capsules: 135.09.31207