

EMEND[®] CAPSULE

Aprepitant (80 mg, 125 mg)

What is in this leaflet

1. What EMEND is taken for
2. How EMEND works
3. Before you take EMEND
4. How to take EMEND
5. While you are taking EMEND
6. Side effects
7. Storage and Disposal of EMEND
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

What EMEND is taken for

EMEND is taken ALONG WITH OTHER MEDICINES to prevent and control nausea (sick feeling) and vomiting caused by your cancer chemotherapy treatment.

How EMEND works

EMEND is a member of a class of medicines called neurokinin 1 (NK₁) receptor antagonists works by blocking signals to the area of the brain that controls nausea and vomiting.

Before you take EMEND

- When you must not take it

- Do not take EMEND if you are allergic to any of its ingredients.

- Before you start to take it

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

- any past or present medical problems.
- any allergies.
- all medicines that you are taking or plan to take, even those you can get without a prescription or herbal products.
- Any intolerance to some sugars as this medicine contains sucrose.

Use in children

Usage of EMEND has not been adequately studied in children. Therefore, EMEND should not be given to children under 18 years old.

Use in the elderly

EMEND works equally well in and is equally well-tolerated by older and younger adults. No dosage adjustment is necessary in the elderly.

- Taking other medicines

Do not take EMEND with medicines containing pimozone (used to treat psychiatric illness), terfenadine, astemizole (used for hay fever and other allergic conditions), or cisapride (used for treating digestive problems). 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)
- rifampin or clarithromycin (antibiotic)
- paroxetine (a medicine used to treat a certain type of depression)
- diltiazem (a medicine used to treat high blood pressure)
- dexamethasone (a type of corticosteroids to treat inflammatory conditions)
- carbamazepine (a medicine used to treat seizures)
- St John's wort (a herbal medicine to treat mental disorder)
- tolbutamide (a medicine used to treat diabetes)

- phenytoin (a medicine used to treat seizures)

How to take EMEND

- How much to take and when to take

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 (Both days after chemotherapy):** Take one 80 mg capsule of EMEND each morning for the 2 days following your chemotherapy treatment.

EMEND may be taken with or without food.

- How long to take

EMEND is taken for 3 days.

- If you forget to take it

Try to take EMEND as prescribed. However, if you miss a dose, contact your physician for further instructions.

- If you take too much (overdose)

If you take more than the prescribed dosage, contact your doctor immediately. Drowsiness and headache were reported in one person who taken too much of aprepitant.

While you are taking EMEND

- Things you must do

Tell your doctor if you are:

- Pregnant or plan to become pregnant.
- Breast-feeding or plan to breast-feed.

EMEND should be taken during pregnancy and breastfeeding only if the potential benefit justifies the

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potential risk to the mother and the fetus.

- Things you must not do

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

- Things to be careful of

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. Talk to your healthcare professional for further information.

Side Effects

Any medicine may have unintended or undesirable effects, so-called side effects.

Like all medicines, EMEND may cause side effects. In studies, side effects usually have been mild or moderate. They generally have not caused people to stop taking EMEND.

The most common side effects in cancer patients taking the 125 mg/80 mg regimen of EMEND included hiccups, fatigue, constipation, headache, indigestion, increased liver enzymes, and loss of appetite.

The following side effects have been reported in general use 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 rarely.

Other side effects may also occur rarely, and as with any other medicines, some side effects may be serious. Ask your doctor or pharmacist for more information. Both have a more complete list of side effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effect / AEFI)

Storage and Disposal of EMEND

- Storage

- Store at or below 30°C.
- Keep EMEND and all medicines safely away from children.

- Disposal

- Do not take this medicine after the date shown by the four numbers following EX (or EXP) on the packaging. The first two numbers indicate the month; the last two numbers indicate the year.
- Do not take EMEND if you notice any changes in the appearance of the products. Contact your doctor or pharmacist.
- 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.
- You may obtain further information from your doctor or pharmacist, who has more detailed information.

Product Description

- What it looks like

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

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

- Ingredients

- Active ingredient:
EMEND 125mg – 125mg
aprepitant per capsule

EMEND 80mg – 80mg
aprepitant per capsule

- Inactive ingredients:

- sucrose
- microcrystalline cellulose
- hydroxypropyl cellulose
- sodium lauryl sulphate
- micronized sodium lauryl sulfate
- microcrystalline cellulose beads

- MAL number

EMEND 125MG –
MAL15065039ACRZ

EMEND 80MG –
MAL15065038ACRZ

Manufacturer

Alkermes Pharma Ireland Limited,
Monksland, Athlone, Co.
Westmeath,
Ireland.

Product Registration Holder

Merck Sharp & Dohme (Malaysia)
Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level 22
The Ascent, Paradigm No. 1
Jalan SS 7/26A, Kelana Jaya

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47301 Petaling Jaya
Selangor, Malaysia.

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