

ONO PHARMACEUTICAL CO., LTD.

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Launch of Antiemetic Drug, EMEND[®] Capsule

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced that an antiemetic drug, EMEND[®] Capsule 125 mg, EMEND[®] Capsule 80 mg, and EMEND[®] Capsule Set (INN: aprepitant), a selective neurokinin-1 (NK₁) receptor antagonist, was launched in Japan today.

The drug was originally discovered by a subsidiary of Merck & Co., Inc., Whitehouse Station N.J. USA, which granted an exclusive license to Ono for development and commercialization in Japan in November 2004, and was approved for marketing on October 16, 2009.

Nausea and vomiting are two common complications of cancer chemotherapy that can lead to considerable distress and disruption in patients' lives. Failure to control these complications often result in aggravation of general conditions or systemic wasting symptoms due to malnutrition and weight loss. In addition, the discomfort by chemotherapy induced nausea and vomiting may lower a patients' Quality of Life (QOL), and interfere with the continuation of chemotherapy. It is therefore extremely important in maintaining the QOL of cancer patients and continuing chemotherapy. Chemotherapy induced nausea and vomiting can occur within the first 24 hours (acute phase) and can continue for several days after that (delayed phase) following emetogenic chemotherapy. Specifically, patients receiving such chemotherapy frequently experience these delayed complications despite the use of currently available anti-vomiting medicines in Japan.

EMEND[®] is the world's first selective neurokinin-1 (NK₁) receptor antagonist for the prevention of these chemotherapy induced complications, and has been demonstrated in clinical trials conducted worldwide including Japan that EMEND[®] works to provide improved prevention against acute as well as delayed nausea and vomiting for which the existing treatments has only insufficient effect.

The launch of EMEND[®] represents a tremendous new treatment for Japanese patients who suffer from chemotherapy induced nausea and vomiting.

EMEND[®] has been approved and marketed in more than 70 countries worldwide including the US, EU member countries as of September 2009. EMEND[®] is recommended as a prophylactic use for nausea and vomiting caused by cancer chemotherapy in antiemetic guidelines issued by cancer associations such as the American Society of Clinical Oncology (ASCO), the Multinational Association of Supportive Care in Cancer (MASCC), and the National Comprehensive Cancer Network (NCCN).

PRODUCT SUMMARY:

Product Name	EMEND [®] Capsule 125 mg, EMEND [®] Capsule 80 mg, EMEND [®] Capsule Set
Generic Name (INN)	aprepitant
Indication	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including in delayed phase)
Dosage and Administration	For oral use, the usual adult dosage of aprepitant, in combination with other antiemetic agents, is 125 mg on Day 1 of administration of an antineoplastic agent, followed by a daily dose of 80 mg from day 2 on.
Product Characteristics	<ol style="list-style-type: none">1. EMEND[®] is the first selective neurokinin-1 (NK₁) receptor antagonist for the prevention of these chemotherapy induced complications.2. Antiemetic effect on digestive symptoms (nausea, vomiting) associated with the administration of antineoplastic agents (cisplatin, etc.) in acute and delayed phase was observed in combination with a corticosteroid and a 5-HT₃ receptor antagonist.3. Adverse reactions including abnormalities of laboratory testing were observed in 135 (42.5%) out of 318 patients studied in the clinical trials performed in Japan, and those include, but not limited to, hiccup in 42 patients (13.2%), elevation of ALT in 39 patients (12.3%), constipation in 32 patients (10.1%), anorexia in 21 patients (6.6%), elevation of AST in 21 patients (6.6%), uric protein in 17 patients (5.3%) and elevation of BUN in 15 patients (4.7%).
Packaging:	EMEND [®] Capsule 80 mg: 6 capsules (blister packaging) EMEND [®] Capsule 125 mg: 6 capsules (blister packaging) EMEND [®] Capsule Set: 1 capsule of 125mg-capsule and 2 capsules of 80mg-capsule in one sheet of blister packaging
NHI reimbursement prices	EMEND [®] Capsule 80 mg: JPY 3,380.90 EMEND [®] Capsule 125 mg: JPY 4,946.00 EMEND [®] Capsule Set: JPY 11,707.80
Date of NHI price listed:	December 11, 2009
Date of launch:	December 11, 2009