

Translation

Antiemetic Agent, Kytril[®], Obtained Approval for Additional Indication

December 22, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on December 22, 2011 for the additional indication of "gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and radiotherapy" for the antiemetic 5-HT₃ receptor antagonist granisetron hydrochloride [brand name: Kytril[®] Tablet 1mg, 2mg, Fine Granule 0.4%, Injection 1mg, 3mg, Intravenous Bag 3mg/50mL and 3mg/100mL, hereafter, "Kytril[®]"]. In Japan, Kytril[®] is currently approved for the indications of "gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration" for oral administration, and "gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and pretreatment with total body irradiation (TBI) for hemopoietic stem cell transplantation" for intravenous injection administration.

As a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs*" held on June 29, an "application based on evidence in the public domain" is applicable when filing for this indication. The decision at the meeting of the First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on July 29, confirmed that filing through the "application based on evidence in the public domain" was reasonable for this additional indication. Thereby, Chugai filed an "application based on evidence in the public domain" for the additional indication on August 10, and obtained approval by the MHLW.

Kytril[®], marketed by Chugai in Japan, was first launched overseas on February 1991 as the antiemetic agent of 5-HT₃ receptor antagonist. In Japan, injection formulation was launched in 1992, and oral formulation was launched in 1995. Nausea and vomiting associated with antineoplastic agent administration and radiotherapy entail pain on the part of the patients. They not only impair their QOL; but also make continuation of treatment itself difficult. Kytril[®] is being positioned as a standard therapy among other treatment options in several guidelines for treating gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agent administration and radiotherapy.

Chugai is convinced that Kytril[®] will provide opportunity for better care to improvement in these patients' QOL, and is committed to contribute to the advancement of cancer therapies

* The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established for the purpose of “enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of “application based on evidence in the public domain” and investigating the need for studies that should be additionally conducted.”

[Reference]

The underlined descriptions are changed.

Brand name: Kytril® Tablet 1mg, Kytril® Tablet 2mg, Kytril® Fine Granule 0.4%
Kytril® Injection 1mg, Kytril® Injection 3mg
Kytril® Intravenous Bag 3mg/50mL, Kytril® Intravenous Bag 3mg/100mL

Generic name: granisetron hydrochloride

Indications: Tablet and Fine Granule
Gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and radiotherapy
Injection and Intravenous Bag
Gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and radiotherapy

Dosage and administration:

Tablet and Fine Granule

The usual adult dosage is 2mg of granisetron once a day orally. The dosage may be adjusted according to the patient's age and symptoms.

Injection and Intravenous Bag

Gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration

Adults: The usual dosage in adults is 40µg/kg as granisetron once a day by intravenous injection or intravenous drip infusion. The dosage may be adjusted according to the patient's age and symptoms. If no symptomatic amelioration is noted, an additional dose of 40µg/kg may be administered once.

Pediatric Use: The usual dosage in children is 40µg/kg as granisetron once a day by intravenous drip infusion. The dosage may be adjusted according to the patient's age and symptoms. If no symptomatic amelioration is noted, an additional dose of 40µg/kg may be administered once.

Gastrointestinal symptoms (nausea and vomiting) associated with radiotherapy

The usual dosage in adults is 40µg/kg as granisetron once a day by intravenous drip infusion. The dosage may be adjusted according to the patient's age and symptoms. The administration should be up to twice a day.

Drug price:	Kytril® Tablet 1mg	JPY 739.5 / Tablet
	Kytril® Tablet 2mg	JPY 1,343.9 / Tablet
	Kytril® Fine Granule 0.4%	JPY 1,364.6 / Pack
	Kytril® Injection 1mg	JPY 2,343 / Ampoule
	Kytril® Injection 3mg	JPY 5,494 / Ampoule
	Kytril® Intravenous Bag 3mg/50mL	JPY 5,667 / Bag
	Kytril® Intravenous Bag 3mg/100mL	JPY 5,667 / Bag

Kytril® is a registered trademark of F. Hoffman-La Roche Ltd.(Switzerland)