

Translation

Immunosuppressive Agent, CellCept[®] Obtains Approval for Additional Pediatric Dosage and Administration for Prophylaxis of Organ Rejection in Renal Transplants

September 16, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter “Chugai”)] announced today that, on September 16, immunosuppressive agent mycophenolate mofetil capsule (brand name: CellCept[®] Capsules 250, hereafter “CellCept[®]”) has obtained approval by the Japanese Ministry of Health, Labour and Welfare for the additional dosage and administration for pediatric patients for the “prophylaxis of organ rejection in patients receiving renal transplants”. In Japan, CellCept[®] is currently marketed with indications for the "treatment of refractory organ rejection after receiving renal transplants", and the "prophylaxis of organ rejection in patients receiving renal, heart, liver, lung or pancreas transplants".

The application based on evidence in the public domain made by Chugai on this occasion, following the meeting of the Review Committee on Unapproved Drugs and Indications with High Medical Needs*, was based on the decision made at the meeting of the First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on April 27, 2011, which confirmed that filing through the application based on evidence in the public domain was reasonable for the “addition of pediatric dosage of CellCept[®] for the prophylaxis of organ rejection in patients receiving renal transplants.”

CellCept[®] has been already approved in Europe and the United States with the indication for the prophylaxis of organ rejection in pediatric patients receiving renal transplants, and is being widely used as one of the standard therapies.

Chugai strongly believes that, as a drug with the indication of pediatric dosage to prevent and suppress organ rejection following renal transplants, where high unmet medical needs exist, CellCept[®] can contribute significantly to the treatment of such patients.

* The Review Committee on Unapproved Drugs and Indications with High Medical Needs was established for the purpose of “enhancing the 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 sections were added and revised.

Brand name: CellCept[®] Capsules 250

Generic name: mycophenolate mofetil

Effects and indications:

- Treatment of refractory organ rejection after receiving renal transplants
(When the patient does not respond to the existing drugs, or can not be treated due to adverse drug reactions, and when the rejections are diagnosed as refractory.)
- Prophylaxis of organ rejections in patients receiving the following organ transplants:
Kidney, heart, liver, lung, or pancreas

Dosage and administration:

1. Renal transplant

- Treatment of refractory organ rejection after receiving renal transplants
The usual adult dosage for oral use is 1,500 mg of mycophenolate mofetil twice a day, once every 12 hours, after meals.
Increase or decrease the dose depending on age and symptoms.
- Prophylaxis of organ rejection in patients receiving renal transplants
Adults: The usual dosage for oral use is 1,000 mg of mycophenolate mofetil twice a day, once every 12 hours, after meals.
Increase or decrease the dose depending on age and symptoms, but make sure that the daily dose does not exceed 3,000 mg.
Children: The usual dosage for oral use is 300 - 600mg/m² of mycophenolate mofetil twice a day, once every 12 hours, after meals.
Increase or decrease the dose depending on age and symptoms, but make sure that the daily dose does not exceed 2,000 mg.

2. Prophylaxis of organ rejection in patients receiving heart, liver, lung or pancreatic transplants

The usual adult dosage for oral use is 500 - 1,500 mg of mycophenolate mofetil twice a day, once every 12 hours, after meals.
However, CellCept[®]'s amount of drug tolerance and effective dose differ, depending on the patient. Therefore, the dose should be carefully increased or decreased to obtain the optimal therapeutic effects.

NHI drug price: 326.2 yen