



Launch of the Immunosuppressant “CellCept® Powder for Oral Suspension 31.8%”

- Different Formulations Can Now Be Selected Based On Patient Needs -

TOKYO, December 21, 2015 - Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it launched “CellCept® Powder for Oral Suspension 31.8%,” a new formulation of the immunosuppressant “CellCept® Capsules 250” (generic name: mycophenolate mofetil) sold for the indication of “Treatment of refractory rejections after kidney transplant” and “Suppression of rejections after the following organ transplants: kidney, heart, liver, lung and pancreas transplants” following its National Health Insurance Drug Price listing on December 11, 2015.

Chugai considered the needs for future transplantation therapy in Japan. We understand that some patients have difficulties in administering the capsule formulation and dosage adjustment. Recognizing that both the powder and capsule formulations are available outside of Japan, in August of 2013, Chugai filed a supplemental application of “CellCept Powder for Oral Suspension 31.8%” so that dosage can be more readily adjusted to suit patient needs. This formulation obtained an approval from the Ministry of Health, Labour and Welfare on August 17, 2015.

Chugai believes that “CellCept Powder for Oral Suspension 31.8%” will contribute to the improvement of patients' satisfaction with treatment. Under its business philosophy “Innovation all for the patients,” Chugai continues to make efforts toward contribution to transplantation therapy.

[Drug information of new formulation]

Brand name: CellCept® Powder for Oral Suspension 31.8%

Generic name: mycophenolate mofetil

- Indications:
- Treatment of refractory rejections after kidney transplant
(When the patient does not respond to the existing drugs, or cannot be treated due to adverse drug reactions, and when the rejections are diagnosed as refractory.)
 - Suppression of rejections after the following organ transplants: kidney, heart, liver, lung and pancreas transplants

Dosage and administration:

1. Kidney transplant

- Treatment of refractory rejection after kidney transplant

The usual dosage for adults is 1,500 mg as mycophenolate mofetil, given orally twice daily every 12 hours after meals.

The dosage should be adjusted depending on age and symptoms of the patient.

- Suppression of rejections after the following organ transplants: kidney, heart, liver, lung and pancreas transplants

Adults: The usual dosage is 1,000 mg as mycophenolate mofetil, given orally twice daily every 12 hours after meals.

The dosage should be adjusted depending on age and symptoms of the patient, with the upper limit of 3,000 mg daily.

Children: The usual dosage is 300 to 600 mg/m² as mycophenolate mofetil, given orally twice daily every 12 hours after meals.

The dosage should be adjusted depending on age and symptoms of the patient, with the upper limit of 2,000 mg daily.

2. Suppression of rejections after heart, liver, lung and pancreas transplants

The usual dosage for adults is 500 to 1,500 mg as mycophenolate mofetil, given orally twice daily every 12 hours after meals.

The dosage should be carefully adjusted to obtain the most therapeutic effect because tolerance and effective dosage of CellCept are different depending on patients.

Drug price: 248.70 yen (200mg/1mL, as liquid for internal use after suspension)