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Translation

Chugai Launches a Long-Acting Erythropoiesis Stimulating Agent, "Mircera® Injection Syringe"

July 19, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that on July 20, it will launch a long-acting erythropoiesis stimulating agent (ESA) [brand name: Mircera® Injection Syringe 25μg, 50μg, 75μg, 100μg, 150μg, 200μg, and 250μg; Japan accepted name (JAN): epoetin beta pegol (genetical recombination) (hereafter, "Mircera® Injection")], which received a manufacturing and marketing approval with indication for use in the treatment of renal anemia on April 22, 2011 and was listed on the National Health Insurance (NHI) reimbursement price list on July 19, 2011.

"Mircera® Injection" is a long-acting ESA that consists of epoetin beta (genetical recombination) and a single molecule of linear methoxy polyethylene glycol (PEG), which are chemically combined. It has a longer serum half-life than other currently available ESAs such as Epogin® Injection, enabling it to maintain hemoglobin levels targeted under the Guideline for Treatment of Renal Anemia* with once-every-four-week intravenous or subcutaneous dosing. A clinical study of this drug has confirmed that it possesses stable anemia improvement and maintenance effects against renal anemia seen in patients who undergo hemodialysis or peritoneal dialysis, as well as in pre-dialysis patients associated with chronic kidney disease.

"Mircera® Injection" was approved in Europe in 2007, and is currently available in more than 100 countries around the world.

Chugai has positioned the renal area as one of the priority areas, and thus expects that "Mircera® Injection," an additional option for the treatment of renal anemia, highly contribute to advancing the treatment of chronic kidney disease, offering improved convenience for the patients such as fewer hospital visits and enhanced quality of life (QOL), and also reducing the burden for healthcare professionals.

*: "Guidelines for renal anemia in chronic kidney disease," 2008 edition released by the Japanese Society for Dialysis Therapy.

[Reference information]

Brand name: Mircera® Injection Syringe 25μg, 50μg, 75μg, 100μg, 150μg, 200μg, and 250μg

Japan accepted name (JAN): epoetin beta pegol (genetical recombination)

Indications: renal anemia

Dosage and administration:

<*Patients undergoing hemodialysis*>

1. Initial dosage
   Usually, 50μg of epoetin beta pegol (genetical recombination) is intravenously administered once every two weeks to adults.
2. Initial dosage when switched from erythropoietin preparations [epoetin alfa (genetical recombination), epoetin beta (genetical recombination)]
   Usually, 100 or 150μg of epoetin beta pegol (genetical recombination) is intravenously administered once every four weeks to adults.
3. Maintenance dosage
   After the anemia improvement effect is observed, usually, 25 to 250μg of epoetin beta pegol (genetical recombination) is intravenously administered once every four weeks to adults.

In any case, the dosage may be changed depending on anemic symptoms, the patient's age, etc., but shall not exceed 250μg at a time.

<*Patients undergoing peritoneal dialysis and with chronic kidney disease at a prior stage of entering dialysis treatment*>

1. Initial dosage
   Usually, 25μg of epoetin beta pegol (genetical recombination) is subcutaneously or intravenously administered once every two weeks to adults.
2. Initial dosage when switched from erythropoietin preparations [epoetin alfa (genetical recombination), epoetin beta (genetical recombination)]
   Usually, 100 or 150μg of epoetin beta pegol (genetical recombination) is subcutaneously or intravenously administered once every four weeks to adults.
3. Maintenance dosage
   After the anemia improvement effect is observed, usually, 25 to 250μg of epoetin beta pegol (genetical recombination) is subcutaneously or intravenously administered once every four weeks to adults.

In any case, the dosage may be changed depending on anemic symptoms, the patient's age, etc., but shall not exceed 250μg at a time.

Date of approval: April 22, 2011

Date of listing in the NHI reimbursement price: July 19, 2011

Date of launch: July 20, 2011

Shelf life: 2 years

NHI price: Mircera® Injection Syringe 25μg 6,969 yen
Mircera® Injection Syringe 50μg 12,507 yen
Mircera® Injection Syringe 75μg 17,608 yen
Mircera® Injection Syringe 100μg 22,445 yen
Mircera® Injection Syringe 150μg 31,600 yen
Mircera® Injection Syringe 200μg 40,281 yen
Mircera® Injection Syringe 250μg 48,625 yen

* “Mircera®” is a registered trademark of F. Hoffmann-La Roche, Ltd.