

NEWS RELEASE



March 15, 2023

Launch of MonoVer[®] for I.V. injection 500mg/1000mg for the treatment of iron deficiency anemia

Kyoto, Japan, March 15, 2023 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced today that it has launched MonoVer[®] for I.V. injection 500mg/1000mg for the treatment of iron deficiency anemia in Japan.

Iron deficiency anemia (IDA) is the anemia caused by iron deficiency and reduction of hemoglobin synthesis associated with heavy uterine bleeding, post-partum hemorrhage, gastrointestinal bleeding, poor absorption of iron through gastrointestinal tract and other relevant diseases. In addition to symptoms such as palpitations, shortness of breath, and easy fatigue due to anemia, concave nails (koilonychia) due to iron deficiency are also observed. To treat IDA, it is fundamental to treat the underlying cause of IDA and replenish iron stores. Regarding iron replenishment, oral iron can be the first choice, and intravenous iron can be selected when oral iron preparations are insufficient due to iron loss caused by massive bleeding, inappropriate to be used due to side effects or poor absorption.

MonoVer[®] is an intravenous iron preparation that contains ferric derisomaltose, a high-stability matrix structure binding with iron and low immunogenicity linear oligosaccharide (derisomaltose), as API. MonoVer[®] is considered to be a choice for the IDA treatment as the maximum single dose 1000 mg enables full iron correction in a short period with few times of infusion.

Nippon Shinyaku licensed in MonoVer[®] from Pharmacosmos A/S (Headquarters, Holbaek, Denmark; President & CEO, Tobias S. Christensen) in December, 2016. Marketing approval of MonoVer[®] was obtained in March, 2022. MonoVer[®] has been approved in 47 countries.

Nippon Shinyaku aims to contribute to the treatment of IDA by appropriately delivering MonoVer[®] to patients.

Summary of MonoVer[®]

Brand name	MonoVer [®] for I.V. injection 500mg MonoVer [®] for I.V. injection 1000mg
Generic name	Ferric Derisomaltose
Date of approval	March 28, 2022
Date of NHI reimbursement price listing	March 15, 2023
Date of launch	March 15, 2023
Number of approval	MonoVer [®] for I.V. injection 500mg: 30400AMX00183000
	MonoVer [®] for I.V. injection 1000mg: 30400AMX00184000
Dosage Forms and Strengths	MonoVer [®] for I.V. Injection 500mg: Aqueous injection containing ferric derisomaltose as ferric iron (500mg) in 1 vial (5mL)
	MonoVer [®] for I.V. Injection 1000mg: Aqueous injection containing ferric derisomaltose as ferric iron (1000mg) in 1 vial (10mL)
Indication	Iron deficiency anemia
Dosage and Administration	<p>Generally, in adults with BW ≥ 50kg, the single dose should be up to 1000mg iron once a week intravenous drip infusion, or up to 500mg iron up to twice a week slow intravenous bolus injections.</p> <p>Generally, in adults with BW < 50kg, the single dose should be up to 20mg/kg iron once a week intravenous drip infusion, or up to 500mg iron up to twice a week slow intravenous bolus injections.</p> <p>While the total iron dose varies by patient's Hb and body weight, the maximum total dose is 2000mg iron (or 1000mg iron in adults with BW < 50kg).</p>
NHI reimbursement price	MonoVer [®] for I.V. injection 500mg: JPY 6,189/vial (500mg/5mL)
	MonoVer [®] for I.V. injection 1000mg: JPY 12,377/vial (1000 mg/10 mL)
Packaging unit	MonoVer [®] for I.V. injection 500mg: 5mL×5 vials
	MonoVer [®] for I.V. injection 1000mg: 10mL×5 vials

About Pharmacosmos A/S

Pharmacosmos Group, headquartered in Holbaek, Denmark, and founded in 1965, is a highly specialized company focused on carbohydrate chemistry and a global leader in the development of innovative treatments for patients suffering from iron deficiency and iron deficiency anemia. With affiliates in the UK, Nordics, Germany, the USA, and China, as well as through partners, Pharmacosmos markets its products across the world. With a strong and ongoing commitment to R&D, Pharmacosmos is able to leverage a unique carbohydrate production platform along with deep expertise in the synthesis of iron-carbohydrate complexes. For more information, please visit <https://www.pharmacosmos.com/>.

About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (<https://www.nippon-shinyaku.co.jp/english/>) for products or detailed information.

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