

Emcure Pharmaceuticals becomes the First Company in India to launch the 750 mg injectable variant of Ferric Carboxymaltose

- Single dose of Ferric Carboxymaltose (FCM) up to 750 mg of iron can be infused in 15 minutes
- Dose suitable for majority of Indian patients with Iron Deficiency and Iron Deficiency Anemia
- Will make it more convenient to Treat Iron Deficiency and Iron Deficiency Anemia in India

Pune, May 15, 2023: Emcure Pharmaceuticals Limited (EPL) has announced the launch of Orofer FCM 750, a new extension of its parenteral iron brand containing Ferric carboxymaltose (FCM).

The new dosage variant is designed to provide a more effective and convenient option for patients with iron deficiency and iron deficiency anaemia (IDA). DCGI-approved FCM is indicated for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. It is already available in dosage forms 1000mg/ 20ml and 500mg/ 10ml single-use vials. With this latest launch, Orofer FCM will also be available as a 750mg/15ml dosage form recommended for treatment of patients with Hemoglobin less than 10 g/dl & bodyweight between 35 kg to 70kg. Orofer FCM can only be obtained through a prescription from a registered medical practitioner.

IDA is a significant burden for women, especially during later trimesters of pregnancy and secondary to postpartum hemorrhage (PPH). Approximately 36% of maternal deaths are attributed to PPH¹ as per Indian studies; whereas anemia during pregnancy is reported among 45.7% and 54.3% of pregnant women in urban and rural areas², respectively, hampering postpartum maternal and early child health outcomes. Indian studies using FCM for the treatment of IDA in pregnancy have indicated that most patients have mean Haemoglobin <10 g/dl.³,4 They may require FCM 1500 mg at body weight between 35-70 kgs. A single dose of FCM up to 750 mg of iron can be infused in a short time frame of 15 minutes diluted in 250 ml of normal saline⁵.

Anil Kothiyal, President India Business at Emcure Pharmaceuticals said "At Emcure Pharmaceuticals, we recognize IDA as a major public health concern in India, particularly among women. We feel satisfied to introduce Orofer FCM 750 to help address this significant burden of IDA in India. This bolsters our commitment to providing innovative and effective solutions to meet the healthcare needs of patients in India. We believe Orofer FCM 750, with its convenient dosage strength, will provide an important treatment option for patients with IDA who may not have responded to oral iron preparations or who cannot tolerate them. Orofer FCM will be available in leading pharmacies and hospitals shortly"

In April 2018, the Intensified National Iron Plus Initiative (I-NIPI) operational guidelines for the "Anemia Mukt Bharat" Programme recommended FCM as the first-line treatment for severe and selected cases of mild-to-moderate anemia in pregnant women in India.⁶ FCM, a unique iron complex consists of a ferric hydroxide core stabilized by a carbohydrate shell, enabling



controlled iron delivery to target tissues. FCM can elevate serum ferritin and Hemoglobin levels and provide better compliance as compared to oral iron and iron sucrose therapy.

Emcure Pharmaceuticals Limited aims to address the unmet medical needs of patients suffering from IDA in India by providing a reliable and convenient treatment option.

- Ends -

References

- 1. Rathod S, Samal SK, Mahapatra PC, Samal S. Ferric carboxymaltose: A revolution in the treatment of postpartum Anaemia in Indian women. Int J Appl Basic Med Res. 2015;5(1):25-30. doi:10.4103/2229-516X.149230
- 2. https://main.mohfw.gov.in/sites/default/files/NFHS-5 Phase-II 0.pdf
- 3. Trivedi P, Chitra S, Natarajan S, et al. Ferric Carboxymaltose in the Management of Iron Deficiency Anemia in Pregnancy: A Subgroup Analysis of a Multicenter Real-World Study Involving 1191 Pregnant Women. *Obstet Gynecol Int.* 2022;2022:5759740. Published 2022 Nov 28. doi:10.1155/2022/5759740
- 4. Charmila A, Natarajan S, Chitra TV, et al. Efficacy and Safety of Ferric Carboxymaltose in the Management of Iron Deficiency Anemia: A Multi-Center Real-World Study from India. J Blood Med. 2022;13:303-313. Published 2022 Jun 8. doi:10.2147/JBM.S361210
- 5. Keating GM. Ferric carboxymaltose: a review of its use in iron deficiency. *Drugs*. 2015;75(1):101-127. doi:10.1007/s40265-014-0332-3
- 6. Anemia Mukt Bharat Anemia management protocol for pregnant women Available from https://anemiamuktbharat.info/home/interventions

About Emcure Pharmaceuticals Ltd:

Emcure Pharmaceuticals Ltd. (EPL) is one of India's leading pharmaceutical players headquartered in Pune with a global footprint. Driven by technology and innovation, the company's mission has been to develop and deliver effective medicines to cure patients, enabling them to lead healthier lives. Established in 1981, the firm was founded by Mr. Satish Mehta who spotted an opportunity in contract manufacturing pharmaceuticals for MNCs. Emcure is ranked as the 13th largest pharma company in India (AIOCD-AWACS MAT Mar 23). It is a leader in gynaecology, blood-related and HIV antiviral therapy areas. It has also developed India's first mRNA vaccine for the novel coronavirus using its in-house indigenously developed mRNA platform.

To know more about Emcure, please visit: https://www.emcure.com/
Follow us on LinkedIn: https://www.linkedin.com/company/emcure-pharmaceuticals-limited/