Nuvifer - a unique, non-salt, oral ferric iron with excellent safety & tolerability for iron deficiency in CKD

NUVIFER®
Ferric Maltol 30 mg Capsule
Mighty Iron with a Feather Touch

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Drug Review

Dosage & Administration

One capsule twice daily on empty stomach or two hours after meals

Iron Deficiency Anaemia in Chronic Kidney Disease (CKD)

- Iron deficiency is the most common cause of anemia globally, accounting for around 50% of the estimated 2.2 billion cases worldwide.[1]
- Anaemia is frequently reported in patients with underlying inflammatory conditions, such as CKD.[1]
- Inflammatory disorders may result in functional iron deficiency, with impaired iron absorption and release, resulting in inappropriate iron availability for erythropoiesis.[2]
- In patients with kidney dysfunction, renal clearance of hepcidin is impaired, resulting in accumulation of hepcidin and disrupt iron absorption and recycling.[3]

Importance of Iron Replacement Therapy

- In iron deficiency, replacement therapy is required to support physiological processes and maintain quality of life, cognitive functioning and the ability to complete daily activities.[4]
- Particularly in patients with underlying inflammatory diseases, long term iron replacement therapy is required to raise and maintain iron stores physiologically, alongside the correction or control of the underlying condition to minimize further loss of iron.[5]

Iron Preparations and Patient's Inconvenience

Oral ferrous iron[1]

- Gastrointestinal adverse events have been widely reported with oral ferrous irons.
- Limited bioavailability of ferrous iron, only 10–20% is estimated to be absorbed.
- Unabsorbed iron forms reactive hydroxyl radicals in the gut, leading to mucosal irritation/damage.
- Unabsorbed iron affects the gut microbiome and can trigger gastrointestinal disease flares.

Intravenous iron[1]

- Administration of IV iron requires admission to hospital.
- Small but potentially serious risks of anaphylaxis, hypophosphatemia and iron overload.

Ferric Maltol - A unique, Non-salt, Oral Ferric Iron with Excellent Safety & Tolerability for Long Term Therapy

- Ferric maltol has been approved by the European Medicines Agency, Swiss Medic and the US FDA for the treatment of iron deficiency, with or without anemia.[1]
- Maltol is a non salt, naturally occurring sugar derivative. It bind with a single ferric iron and form ferric maltol complex, which is stable at a physiologic pH and remains strongly chelated until the point of absorption in the gut.[6]
- There is no free iron in the gut to generate hydroxyl radicals, minimizing the risk of gastrointestinal toxicity, reducing the risk of damage to the gut microbiome and exacerbation of any underlying gastrointestinal disease.[7]
- Prolonged treatment with ferric maltol provides sufficient iron to meet the body's erythropoietic needs, which could help reduce the need for erythropoiesis-stimulating agents or blood transfusions.[1]

Proven Result and Safety

- In CKD ferric maltol is an effective and efficacious oral therapy for patients with iron deficiency and anemia.[1]
- In CKD study, overall incidence of adverse events was lower with ferric maltol (68%) than with the placebo (75%).[8]
- Ferric maltol statistically increased hemoglobin, ferritin, and TSAT levels in patients with stage 3 and 4 CKD by week 16 and improvements were maintained over 52 weeks.[9]
- More effective iron absorption from the ferric maltol complex was recorded when iron was in the ferric versus ferrous form.[10]

Proven Result and Safety (Cont...)

- Ferric maltol has protective effect of on the gut microbiome and an avoidance of free iron-induced intestinal damage.[7]
- Ferric maltol is an appropriate treatment option for patients in whom long-term, convenient, and well-tolerated management of chronic iron deficiency is needed.[1]

In Iron deficiency & Iron deficiency anemia

A unique, non-salt, oral ferric iron

with excellent safety and tolerability for long term treatment

NUVIFER®

Ferric Maltol 30 mg Capsule

Mighty Iron with a Feather Touch

Mighty Iron

Low Dose

- 30 mg capsule twice daily

Powerful Hemoglobin improvement

- 2.25 gm/dL in just 12 weeks[5]

In Pregnancy

- According to **ueg Week, October 2023**, Ferric Maltol has favorable efficacy & safety profile[6]

Feather Touch

Does not require the conversion of ferric to ferrous[1-4]

Improved compliance than conventional ferrous salt[1-4]

- No Free Iron
- No Hydroxyl Radicals

… offers powerful efficacy with high GI tolerability for long-term treatment compliance

℞ in

☑ CKD ☑ Pregnancy ☑ Heart failure ☑ IBD ☑ Cancer ☑ Surgery

Ref.: **1.** Schmidt C, Allen S, Kopyt N, Pergola P. Iron Replacement Therapy with Oral Ferric Maltol: Review of the Evidence and Expert Opinion. J Clin Med. 2021 Sep 28;10(19):4448. doi: 10.3390/jcm10194448. PMID: 34640466; PMCID: PMC8509126.; **2.** Lopez A., Cacoub P., Macdougall I.C., Peyrin-Biroulet L. Iron deficiency anaemia. Lancet. 2016;387:907–916. doi: 10.1016/S0140-6736(15)60865-0.; **3.** Ganz T., Nemeth E. Hepcidin and iron homeostasis. Biochim. Biophys. Acta. 2012;1823:1434–1443. doi: 10.1016/j.bbamcr.2012.01.014.; **4.** Dignass A.U., Gasche C., Bettenworth D., Birgegård G., Danese S., Gisbert J.P., Gomollon F., Iqbal T., Katsanos K., Koutroubakis I., et al. European consensus on the diagnosis and management of iron deficiency and anaemia in inflammatory bowel diseases. J. Crohn's Colitis. 2015;9:211–222. doi: 10.1093/ecco-jcc/jju009.; **5.** Gargallo-Puyuelo C.J., Alfambra E., García-Erce J.A., Gomollon F. Iron treatment may be difficult in inflammatory diseases: Inflammatory bowel disease as a paradigm. Nutrients. 2018;10:1959. doi: 10.3390/nu10121959.; **6.** Kelsey S., Hider R., Bloor J., Blake D., Gutteridge C., Newland A. Absorption of low and therapeutic doses of ferric maltol, a novel ferric iron compound, in iron deficient subjects using a single dose iron absorption test. J. Clin. Pharm. Ther. 1991;16:117–122. doi: 10.1111/j.1365-2710.1991.tb00292.x.; **7.** Mahalhal A., Frau A., Burkitt M.D., Ijaz U.Z., Lamb C.A., Mansfield J.C., Lewis S., Pritchard D.M., Probert C.S. Oral ferric maltol does not adversely affect the intestinal microbiome of patients or mice, but ferrous sulphate does. Nutrients. 2021;13:2269. doi: 10.3390/nu13072269.; **8.** Pergola P.E., Kopyt N.P. Oral ferric maltol for the treatment of iron-deficiency anemia in patients with chronic kidney disease: Phase 3, multicenter, randomized, placebo-controlled trial and open-label extension. Am. J. Kidney Dis. 2021 doi: 10.1053/j.ajkd.2021.03.020. (Epub ahead of print).; **9.** Howaldt S, Domènech E, Martinez N, Schmidt C, Bokemeyer B. Long-Term Effectiveness of Oral Ferric Maltol vs Intravenous Ferric Carboxymaltose for the Treatment of Iron-Deficiency Anemia in Patients With Inflammatory Bowel Disease: A Randomized Controlled Noninferiority Trial. Inflamm Bowel Dis. 2022 Mar 2;28(3):373-384. doi: 10.1093/ibd/izab073. Erratum in: Inflamm Bowel Dis. 2022 Mar 2;28(3):494. doi: 10.1093/ibd/izab224. PMID: 33988236; PMCID: PMC8889281.; **10.** Barrand M.A., Callingham B.A., Hider R.C. Effects of the pyrones, maltol and ethyl maltol, on iron absorption from the rat small intestine. J. Pharm. Pharmacol. 1987;39:203–211. doi: 10.1111/j.2042-7158.1987.tb06249.x.

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