IRON THEY'LL ACTUALLY TAKE[1]

#1 prescribed FDA-approved branded oral iron treatment for adults,[2] and **first and only FDA-approved oral iron for children 10 years of age and older.**[3]

ACCRUFeR® (ferric maltol) has a unique MALTOL SHIELD™ that protects iron from oxidizing as it passes through the stomach, resulting in unprecedented GI tolerability and clinically proven efficacy.[4,5]

Not actual patients.

ACCRUFeR®
(ferric maltol) *30 mg capsules*

INDICATIONS AND USAGE

ACCRUFeR (ferric maltol) is indicated for the treatment of iron deficiency in adults and pediatric patients 10 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ACCRUFeR is contraindicated in patients with a history of:

- Hypersensitivity to ACCRUFeR or any of its inactive components
- Hemochromatosis and other iron overload syndromes
- Receiving repeated blood transfusions as this may result in iron overload

Please see Important Safety Information throughout and accompanying full Prescribing Information.

PATIENTS WITH ID/IDA NEED TOLERABLE AND EFFECTIVE TREATMENT

In the United States, about 10 million people have iron deficiency (ID) and about 5 million have iron deficiency anemia (IDA).[6]

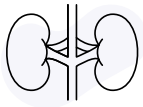
Prevalence is highest in women of childbearing age and patients with inflammatory conditions.[7]

Women's health

- Menorrhagia
- Pregnancy
- Uterine Fibroids

Inflammatory bowel disease

- Crohn's disease
- Ulcerative colitis



Chronic kidney disease

Traditional oral iron supplements (ferrous salts) often cause GI side effects because they release free Fe^{2+} ions in the stomach that can:

- Clump together, becoming difficult to absorb[8]
- Oxidize to generate reactive oxygen species (ROS) that irritate and damage the intestinal lining, contributing to GI discomfort[5,9,10]

Additionally, free iron in the colon can have adverse impacts on the gut microbiome, adding to the inflammation with which IBD patients are already dealing.[11]

Up to **60%** of patients will **discontinue treatment** with ferrous salts.[12]

More than two-thirds of people taking traditional oral iron report GI issues, such as:[13,14]

- Heartburn
- Loss of appetite
- Stomach cramps
- Nausea
- Diarrhea
- Discolored stool
- Flatulence
- Constipation

WHY ACCRUFeR?

ACCRUFeR is an FDA-approved treatment that delivers a low dose of elemental iron that can reverse IDA while minimizing risk for unmanageable GI side effects.[4]

ACCRUFeR's MALTOL SHIELD™ reduces free iron in the gut — promoting absorption and GI tolerability[4,8,15]

Unprecedented tolerability

In clinical studies, 4.6% of patients taking ACCRUFeR (n=175) discontinued treatment due to adverse reactions, compared with 2.5% of patients taking a placebo (n=120).[4]

Established safety and efficacy

FDA approval was achieved based on three pivotal studies in patients with ID/IDA associated with chronic inflammation and malabsorption, resulting in **significant improvement across iron indices**, including hemoglobin, ferritin, and TSAT.*[4,8,10]

**Not to be used by patients with an active IBD flare*

Committed to affordability

Eligible patients may **pay as little as $0** for ACCRUFeR.*

** Restrictions apply.*

WARNINGS AND PRECAUTIONS

Increased Risk of Inflammatory Bowel Disease (IBD) Flare

Avoid use of ACCRUFeR in patients with an active IBD flare, as there is potential risk of increased inflammation in the gastrointestinal tract.

Iron Overload

Excessive therapy with iron products can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Do not administer ACCRUFeR to patients with evidence of iron overload or patients receiving intravenous iron. Assess iron parameters prior to initiating ACCRUFeR and monitor iron parameters while on therapy.

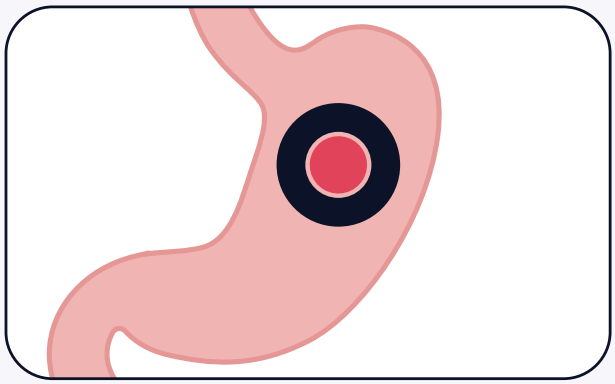
Please see Important Safety Information throughout and accompanying full Prescribing Information.

UNIQUELY FORMULATED WITH A MALTOL SHIELD™

ACCRUFeR is a stable complex of ferric iron (Fe^{3+}) and maltol, a naturally occurring sugar derivative. Unlike iron salts, this iron-sugar derivative complex stays intact in the stomach, dissociating when it reaches the duodenum for optimal iron absorption.[4]

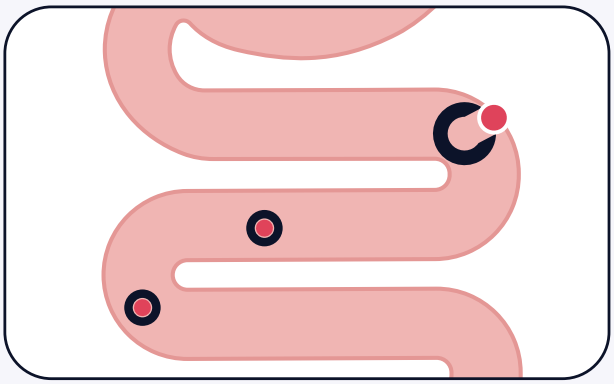
ACCRUFeR in Action

Tightly bound in the stomach[4,8]



The MALTOL SHIELD™ protects iron from oxidizing in the stomach, remaining tightly bound as it passes through.

Dissociates upon uptake in the duodenum[4,8]



Iron remains bioavailable, chelated, and ready to replenish iron stores.

Excess ACCRUFeR is excreted in the stool.[4]

MALTOL SHIELD™

ACCRUFeR's MALTOL SHIELD™ reduces free iron in the gut — promoting absorption and GI tolerability[4,8,15] lowering the risk of[5]:

- Iron clumping, which can lead to poor absorption
- Oxidation, which generates ROS and causes GI irritation[5,9,10]

Risk of Overdosage in Children Due to Accidental Ingestion

Accidental overdose of iron products is a leading cause of fatal poisoning in children under age 6.

Keep out of reach of children.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

UNPRECEDENTED TOLERABILITY AND ESTABLISHED SAFETY

In clinical studies, GI adverse reactions were mild to moderate in nature, and less than 5% of patients reported individual GI adverse reactions.[4]

Pooled Results from AEGIS IBD and AEGIS CKD

Adverse reactions reported by ≥1% of patients treated with ACCRUFeR during the double-blind period of placebo-controlled studies[4]

Overall, the safety profile reported in pediatric patients was consistent with the safety profile reported in adult patients with iron deficiency anemia.[4]

Gastrointestinal Adverse Reactions	ACCRUFeR (n=175)	Placebo (n=120)
Flatulence	4.6%	0%
Diarrhea	4%	1.7%
Constipation	4%	0.8%
Discolored feces	4%	0.8%
Abdominal pain	2.9%	2.5%
Nausea	1.7%	0.8%
Vomiting	1.7%	0%
Abdominal discomfort	1.1%	0%
Abdominal distension	1.1%	0%

Excluding open-label extension period

In clinical trials, **4.6%** of patients (n=175) discontinued ACCRUFeR because of adverse reactions compared to 2.5% of patients (n=120) on placebo.[4]

ADVERSE REACTIONS

Most common adverse reactions (≥1%) reported with ACCRUFeR during the double-blind, placebo-controlled portions of the pivotal trials were flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting, and abdominal discomfort/distension.

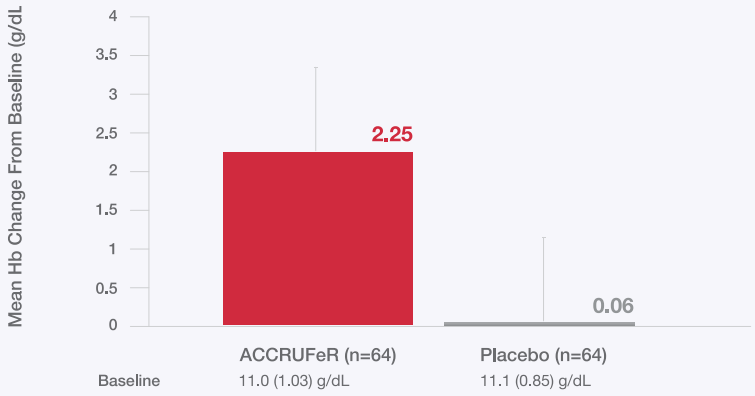
To report adverse events, please contact Shield Therapeutics at 1-888-963-6267. You may also contact the FDA at **www.fda.gov/medwatch** or **1-800-FDA-1088**.

SIGNIFICANT AND RAPID IMPROVEMENTS IN HEMOGLOBIN IN ADULTS WITH IBD

ACCRUFeR established safety and efficacy in patients with Crohn's disease and ulcerative colitis in two 12-week, phase 3A, randomized and placebo-controlled pivotal trials with a 52-week open label extension phase **in patients that had previously failed treatment with oral ferrous products**.[1,4,10]

Primary Endpoint: LS Mean (SE) Hb Concentration from Baseline to Week 12

One-sided 97.5% CI, 1.81; P<0.0001 based on ANCOVA



2.25 (0.12) g/dL LS mean (SE) improvement in Hb in the ACCRUFeR group vs 0.06 (0.13) in the placebo.[4]

Statistical significance was achieved as early as **Week 4**.

ACCRUFeR Increased Hb, Ferritin, and TSAT

		ACCRUFeR (n=64)	**Placebo** (n=64)
Primary Endpoints: LS mean (SE) change from Baseline (BL) Hb to week 12[4]	**Hb** (g/dL)	**+2.25 (0.12)** BL: 11.0 (1.03)	**+0.06 (0.13)** BL: 11.10 (0.85)
Secondary Endpoints: Mean (SD) change from baseline ferritin and TSAT to week 12[4,10]	**Ferritin** (mcg/L)	**+17.3 (28.30)** BL: 8.6 (6.8)	**+1.2 (7.85)** BL: 8.2 (6.5)
	TSAT (%)	**+18 (20.2)** BL: 10.6 (11.7)	**-0.4 (7.8)** BL: 9.5 (7.5)

DRUG INTERACTIONS

- Avoid concomitant use with dimercaprol
- Separate administration of ACCRUFeR from certain oral medications where interaction might occur. Monitor clinical responses as appropriate

Please see Important Safety Information throughout and accompanying full Prescribing Information.

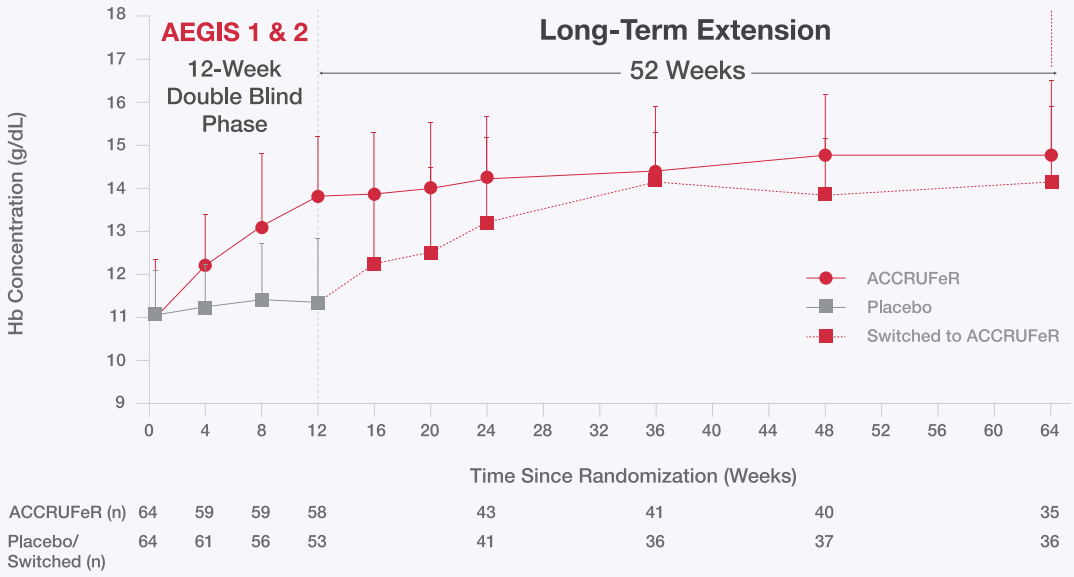
IMPROVEMENTS IN Hb WERE MAINTAINED UP TO 64 WEEKS

At Week 12, patients on placebo switched to ACCRUFeR, and patients already on treatment continued for an additional 52 weeks.[1,4]

Mean Improvement in Hb from Baseline to Week 64

Hb in patients on ACCRUFeR (n=35)	Hb in patients on placebo who switched after Week 12 (n=36)
+3.07 (1.46) g/dL	+2.19 (1.61) g/dL

Absolute Hb Concentrations from Baseline to Week 64



At Week 64 **86%** Cumulative proportion of patients (n=128) **maintained normal Hb**.[1]

WARNINGS AND PRECAUTIONS

Increased Risk of Inflammatory Bowel Disease (IBD) Flare

Avoid use of ACCRUFeR in patients with an active IBD flare, as there is potential risk of increased inflammation in the gastrointestinal tract.

Iron Overload

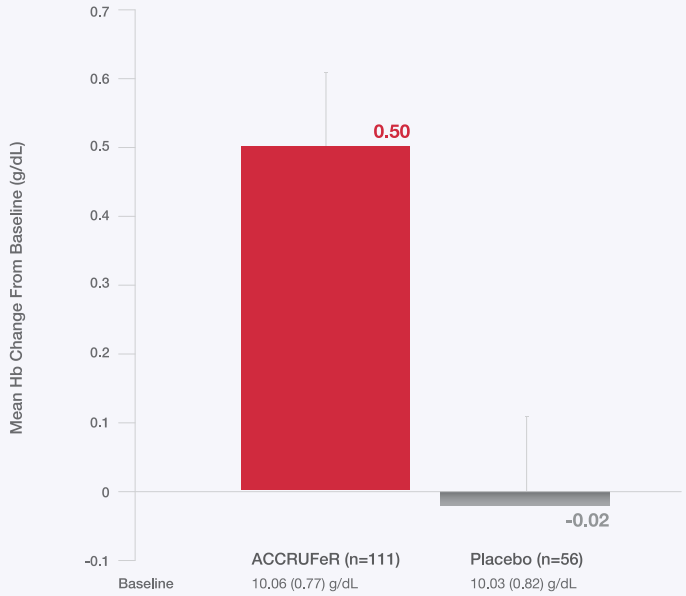
Excessive therapy with iron products can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Do not administer ACCRUFeR to patients with evidence of iron overload or patients receiving intravenous iron. Assess iron parameters prior to initiating ACCRUFeR and monitor iron parameters while on therapy.

SIGNIFICANT IMPROVEMENTS IN HEMOGLOBIN IN ADULTS WITH CKD[4,8]

ACCRUFeR established safety and efficacy in patients with stage 3 or 4 chronic kidney disease (CKD), **excluding those on erythropoiesis-stimulating agents**, in a 16-week, phase 3A, randomized and placebo-controlled pivotal trial with a 36-week open label extension phase.

Primary Endpoint: LS Mean (SE) Change in Hb at Week 16

95% CI: 0.10, 0.93; P=0.0149



0.52 (0.21) g/dL improvement in Hb in patients taking ACCRUFeR vs placebo.

ACCRUFeR Increased Hb, Ferritin, and TSAT

		ACCRUFeR (n=111)	**Placebo** (n=56)
Primary Endpoints: LS mean (SE) change from Baseline (BL) Hb to week 16[4]	**Hb** (g/dL)	**+0.50 (0.12)** BL: 10.1 (0.77)	**-0.02 (0.16)** BL: 10.0 (0.82)
Secondary Endpoints: LS mean (SE) change from baseline ferritin and TSAT to week 16[4,8]	**Ferritin** (mcg/L)	**+25.4 (5.4)** BL: 97.0 (88.5)	**-7.2 (7.7)** BL: 104.2 (80.0)
	TSAT (%)	**+3.8 (0.6)** BL: 15.7 (6.4)	**-0.9 (0.9)** BL: 15.6 (5.9)

CONTRAINDICATIONS

ACCRUFeR is contraindicated in patients with a history of:

- Hypersensitivity to ACCRUFeR or any of its inactive components
- Hemochromatosis and other iron overload syndromes
- Receiving repeated blood transfusions as this may result in iron overload

Please see Important Safety Information throughout and accompanying full Prescribing Information.

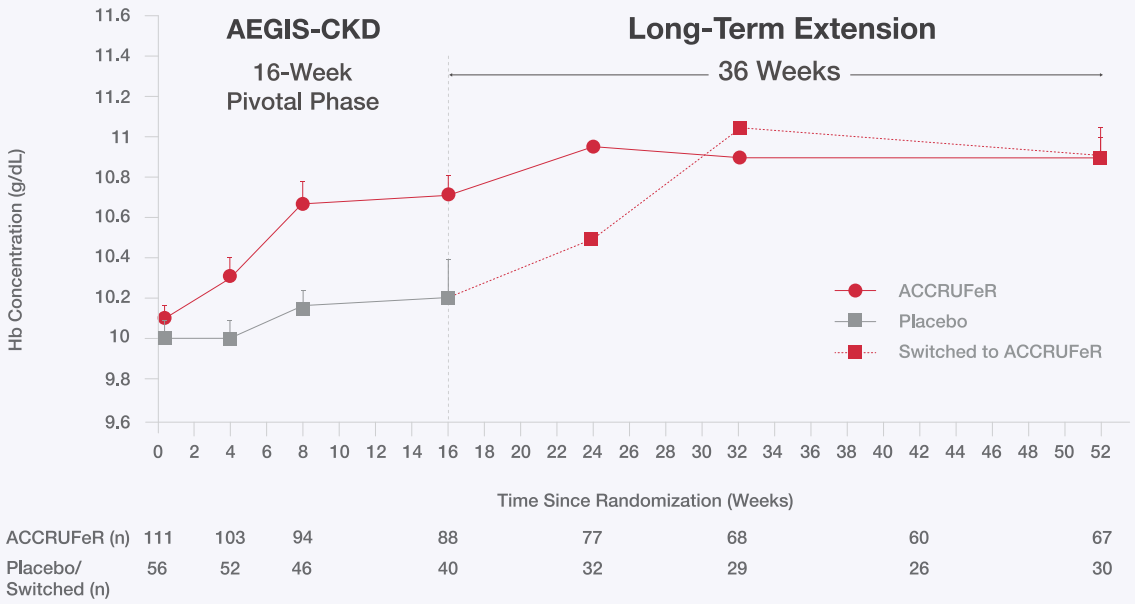
INCREASED Hb CONCENTRATIONS WERE MAINTAINED OVER 52 WEEKS

At Week 16, patients on placebo switched to ACCRUFeR, and patients already on treatment continued for an additional 36 weeks.[4,8] Increases in Hb for patients taking ACCRUFeR at Weeks 4,8, and 16 were consistent with changes seen in the AEGIS-IBD studies.[1,4]

Mean Improvement in Hb from Baseline to Week 52

Hb in patients on ACCRUFeR (n=67)	**Hb in patients on placebo who switched after Week 12** (n=30)
+0.7 (1.7) g/dL	**+0.5** (1.4) g/dL

Absolute (SE) Hb Concentrations in Patients Over 52 Weeks



Neither short- nor long-term treatment led to iron overload.[1,8,10]

ADVERSE REACTIONS

Most common adverse reactions (≥1%) reported with ACCRUFeR during the double-blind, placebo-controlled portions of the pivotal trials were flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting, and abdominal discomfort/distension.

To report adverse events, please contact Shield Therapeutics at 1-888-963-6267. You may also contact the FDA at **www.fda.gov/medwatch** or **1-800-FDA-1088**.

ACCRUFeR IS THE ONLY FDA-APPROVED ORAL IRON FOR CHILDREN AGED 10 YEARS AND OLDER[3]

Population	Study Description		ACCRUFeR
Children 10 - <18 Years[2]	• 12-week, open label study • 24 patients aged 10 to <18 years with IDA • Primary endpoint: Mean (SD) change in Hb from baseline to week 12	**Hb** (g/dL) Primary Endpoint	+1.10 (1.06) BL: 10.73 (0.89)
		Ferritin (mcg/L) Secondary Endpoint	+8.6 (10.29) BL: 11.4 (10.06)

PATIENTS TAKE ONE 30-MG, GLUTEN-FREE CAPSULE BID[4]

Treatment considerations[4]

- Advise patients to take ACCRUFeR 1 hour before or 2 hours after a meal.
- Treatment duration depends on deficiency severity; at least 12 weeks of treatment is typically needed.
- Treatment with ACCRUFeR should be continued until ferritin levels are within normal ranges.
- Stool softener or other supplements, like vitamin C, are not required.

97% median overall treatment compliance rate was seen across a 12-week and 52-week open label extension.[1]

START YOUR PATIENTS ON ACCRUFeR

We're committed to making ACCRUFeR affordable. **Scan the QR code below to learn more.**

About AEGIS IBD

STUDY DESCRIPTION The study enrolled 128 IBD patients (58 ulcerative colitis, 70 Crohn's disease) with IDA across 2 studies. Hb concentrations were between 9.5 g/dL and 12/13 g/dL for females/males and ferritin <30 mcg/L. A responder analysis was done defining treatment responders as patients who achieved increases in Hb of ≥1 g/dL or ≥2 g/dL, or Hb normalization by Week 12. Normalization of Hb was defined based on Hb values ≥12 g/dL for females or ≥13 g/dL for males. **STUDY ENDPOINTS** Primary endpoint: Mean difference in Hb concentration from baseline to Week 12 between ACCRUFeR and placebo. Secondary endpoints: Changes in Hb concentration from baseline to Weeks 4 and 8, serum ferritin concentration, and TSAT. **BASELINE CHARACTERISTICS** Mean age: 38.5 (placebo) to 40.1 (ACCRUFeR) years. Gender and ethnicity: 45 males and 83 females; 122 white and 6 others.

About AEGIS CKD

STUDY DESCRIPTION The study included 167 stage 3 or 4 CKD patients with IDA that were randomized 2:1 (ACCRUFeR to placebo). **STUDY ENDPOINTS** Primary endpoint: The mean difference in Hb concentration from baseline to Week 16 between ACCRUFeR and placebo. Secondary endpoints: Proportions of patients with Hb increases of at least 1 g/dL and at least 2 g/dL at Week 16; the proportion of patients achieving a Hb concentration of at least 11.0 g/dL at Week 16; change in Hb concentration from baseline to Weeks 4 and 8; and changes in ferritin, TSAT, and serum iron measures at Weeks 4, 8, and 16. **BASELINE CHARACTERISTICS** Mean age: 65.2 (placebo) to 68.5 (ACCRUFeR) years, range 30-90 years. Gender and ethnicity: 50 males and 117 females; 123 White, 35 African American, and 9 other.

REFERENCES

1. Schmidt C, Ahmad T, Tulassay Z, et al. Ferric maltol therapy for iron deficiency anaemia in patients with inflammatory bowel disease: long-term extension data from a phase 3 study. *Aliment Pharmacol Ther*. 2016;44(3):259-270. doi:10.1111/apt.13665**. 2.** Data on File. Shield Therapeutics Inc. 2025. **3.** FDA.gov. www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-prescription-oral-medicine-iron-deficiency-pediatric-patients-ages-10-and-older. Published 2025. Accessed April 2026. **4.** ACCRUFeR® full prescribing information. Shield Therapeutics, 2025. **5.** Stallmach A, Büning C. Ferric maltol (ST10): a novel oral iron supplement for the treatment of iron deficiency anemia in inflammatory bowel disease. *Expert Opin Pharmacother*. 2015;16(18):2859-2867. doi:10.1517/14656566.2015.1096929. **6.** Miller JL. Iron deficiency anemia: a common and curable disease. *Cold Spring Harb Perspect Med*. 2013;3(7):a011866. doi:10.1101/cshperspect.a011866. **7.** Cappellini MD, Musallam KM, Taher AT. Iron deficiency anemia revisited. *J Intern Med*. 2020;287(2):153-170. doi:10.1111/joim.13004. **8.** Pergola PE, Kopyt NP. Oral ferric maltol for the treatment of iron-deficiency anemia in patients with CKD: a randomized trial and open-label extension. *Am J Kidney Dis*. 2021;78(6):846-856.e1.doi:10.1053/j.ajkd.2021.03.020 **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*. 2021;28(3):373-384. doi:10.1093/ibd/izab073. **10.** Gasche C, Ahmad T, Tulassay Z, et al. Ferric maltol is effective in correcting iron deficiency anemia in patients with inflammatory bowel disease: results from a phase-3 clinical trial program. *Inflamm Bowel Dis*. 2015;21(3):579-588. doi:10.1097/mib.0000000000003146. **11.** Yilmaz B, et al. *Pharmaceuticals (Basel)*. 2018;11(4):98. **12.** Cancelo-Hidalgo MJ, Castelo-Branco C, Palacios S, et al. Tolerability of different oral iron supplements: a systematic review. Curr Med Res Opin. 2013;29(4):291-303. doi: 10.1185/03007995.2012.761599. **13.** DeLoughery TG. Safety of oral and intravenous iron. *Acta Haematologica*. 2019;142(1):8-12. doi:10.1159/000496966. **14.** Tolkien Z, Stecher L, Mander AP, Pereira DI, Powell JJ. Ferrous sulfate supplementation causes significant gastrointestinal side-effects in adults: a systematic review and meta-analysis. *PLoS One*. 2015;10(2);e0117383. doi:10.1371/journal.pone.0117383. **15.** European Medicines Agency. Assessment report: Feraccru. www.ema.europa.eu/en/documents/variation-report/feraccru-h-c-2733-ii-0010-epar-assessment-report-variation_en.pdf; Published 2018. Accessed April 2026.