



IRON YOU'LL **ACTUALLY TAKE**

ACCRUFer[®] (ferric maltol) has a unique “maltol shield” designed to protect iron from the stomach, so it doesn't break down until it is ready to be absorbed in the small intestine. This reduces the risk of side effects such as gas, diarrhea, nausea, and constipation.¹

ACCRUFer is a prescription medicine used in adults to treat low iron stores in your body. It is not known if ACCRUFer is safe and effective for use in children.¹

Please see Important Safety Information throughout this brochure and full Prescribing Information about ACCRUFer on the last two pages.

IMPORTANT SAFETY INFORMATION

Do not take ACCRUFer if you are allergic to ferric maltol or any of the ingredients in ACCRUFer; have any illness that causes you to store too much iron in your body or if you have a problem with how your body uses iron; are receiving repeated blood transfusions.

GIVE YOUR STOMACH A BREAK

Common oral iron supplements often lead to gastrointestinal (GI) upset and irritation.



Up to **70%** of people taking traditional iron products report GI issues such as:^{2,3}

Constipation | Loss of appetite | Stomach cramps
Nausea | Heartburn | Diarrhea | Discolored stools | Gas



Up to **60%** of patients will not stick to treatment with iron supplements because of side effects.⁴

ACCRUFer works differently — its “maltol shield” keeps the iron protected from the stomach until its absorbed in the small intestine, which leads to unprecedented tolerability.¹



IMPORTANT SAFETY INFORMATION (cont.)

Before you take ACCRUFer, tell your doctor about all your medical conditions, including if you have inflammatory bowel disease (IBD); are pregnant or plan to become pregnant (it is not known if ACCRUFer will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if ACCRUFer passes into your breast milk); talk to your doctor about the best way to feed your baby if you take ACCRUFer.

SEE WHAT SETS ACCRUFer APART

You deserve an iron you can tolerate. Here are a few reasons why ACCRUFer may be right for you:



Iron with a shield

The “maltol shield” keeps iron protected from the stomach, so it doesn’t break down until it is ready to be absorbed in the small intestine. This reduces the risk of GI side effects such as gas, diarrhea, and nausea.¹



Unprecedented tolerability

Across three clinical trials, fewer than 5% of patients stopped taking ACCRUFer because of GI side effects.*^{1,5}

*Total of 175 patients across studies



Backed by clinical data

ACCRUFer achieved FDA approval based on three clinical studies that established its safety and effectiveness in treating ID and IDA.^{1,6,7}



Multiple ways to save

We’re committed to making ACCRUFer affordable. Learn more at [ACCRUFer.com](https://www.ACCRUFer.com)

IMPORTANT SAFETY INFORMATION (cont.)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ACCRUFer and certain other medicines may interact, which could potentially cause serious side effects. Some medicines may need to be taken at least 4 hours before or 4 hours after you have taken ACCRUFer. Ask your health-care provider for a list of these medicines if you are not sure if you take one of these medicines.

ARE YOU IRON DEFICIENT?

The symptoms of ID and IDA can include gas, diarrhea, nausea, and constipation. Left untreated, ID and IDA can lead to serious health problems.¹



To learn more about common symptoms of ID/IDA and whether ACCRUFeR may be a good treatment option for you, visit www.accrufer.com or scan the QR code.

If any of these symptoms sound familiar, ask your doctor to check your iron levels with a blood test. If the results indicate ID or IDA, your doctor will discuss treatment options with you, such as:¹

- **ACCRUFeR (ferric maltol):** This is the only oral iron treatment approved by the U.S. Food and Drug Administration (FDA) for adults with ID/IDA, regardless of underlying condition.
- **Oral iron supplements:** While there are a variety of over-the-counter options, supplements are not evaluated by the FDA to diagnose, treat, prevent, or cure ID or IDA.

IMPORTANT SAFETY INFORMATION (cont.)

Especially tell your healthcare provider if you take:

- Dimercaprol
- Other oral iron tablets or health supplements containing iron

Ask your healthcare provider if you are not sure if you take one of these medicines. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

WHO IS MOST AT RISK FOR ID OR IDA?

ID and IDA can happen when:^{8,9}



You have a condition that is making it difficult for your body to absorb iron (e.g., Crohn's disease).



Your body is losing iron through blood loss (e.g., heavy periods).



Your body is going through changes that require a lot of iron (e.g., pregnancy).



Your diet doesn't provide enough iron (e.g., some vegan or vegetarian diets).



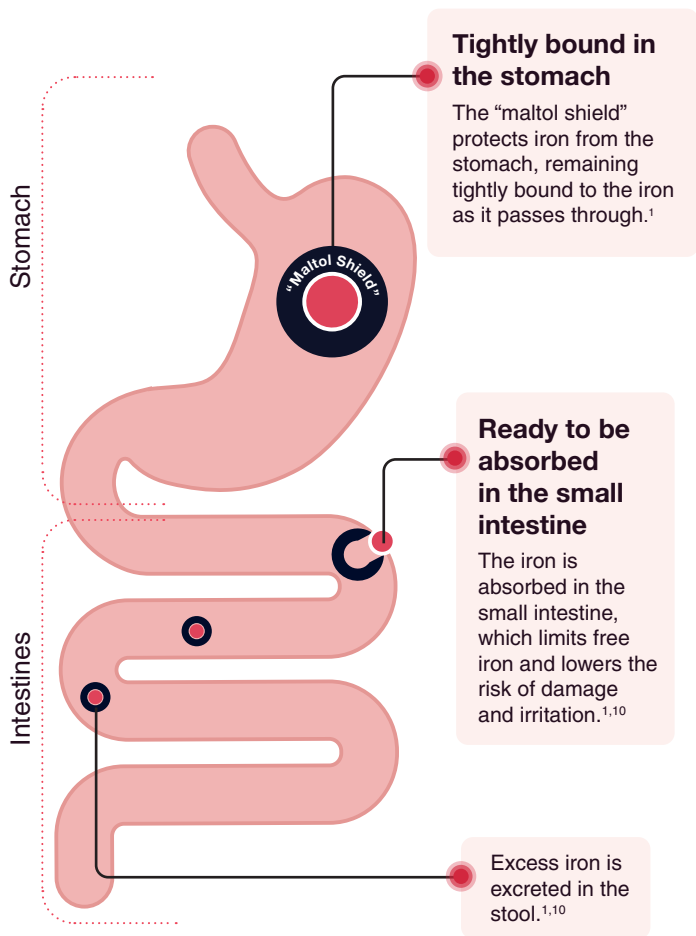
IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of ACCRUFeR?

ACCRUFeR may cause serious side effects including:

- Increased risk of inflammatory bowel disease (IBD) flare. You should avoid taking ACCRUFeR if you have IBD and are experiencing a flare.

HOW DOES ACCRUF_eR WORK?



IMPORTANT SAFETY INFORMATION (cont.)

- Too much iron stored in your body (iron overload). Your healthcare provider should check the iron level in your blood before you start treatment with ACCRUF_eR

OUR CLINICAL STUDIES

ACCRUF_eR was studied in multiple clinical trials that measured indicators of iron levels such as hemoglobin, TSAT, and ferritin over the course of a year.⁶

ACCRUF_eR RAPIDLY RETURNED HEMOGLOBIN LEVELS TO NORMAL¹²



BY WEEK 4

one-third of people taking ACCRUF_eR had normal hemoglobin levels¹¹



BY WEEK 12

three-quarters of people taking ACCRUF_eR had normal hemoglobin levels⁶

ACCRUF_eR also improved other markers (such as ferritin and TSAT) that show iron stores are being built up over the course of the study.⁶



TSAT, percentage transferrin saturation.

IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of ACCRUF_eR?

ACCRUF_eR may cause serious side effects including:

- Risk of overdose in children due to accidental swallowing. Accidental overdose of iron-containing products is a leading cause of death from poisoning in children under 6. Keep ACCRUF_eR in a safe place and out of the reach of children.

TAKING ACCRUF_eR

Take one 30 mg gluten-free capsule twice a day.¹



Stool softeners and supplements, such as vitamin C, are not needed to help ACCRUF_eR work or to manage side effects.

How should you take ACCRUF_eR?¹

- Take ACCRUF_eR exactly as your doctor tells you. Tell your doctor about any medical conditions and medicines that you currently take, including over-the-counter medications, vitamins, and herbal supplements.
- Take ACCRUF_eR twice a day on an empty stomach. This may be 1 hour before or 2 hours after a meal.
- Swallow capsules whole. Do not open, break, or chew the capsules.

Please review the Patient Information section at the end of this brochure for more information.

IMPORTANT SAFETY INFORMATION (cont.)

The most common side effects of ACCRUF_eR include gas, diarrhea, constipation, discolored stools, stomach pain, nausea, vomiting, and stomach area discomfort or bloating. These are not all the possible side effects of ACCRUF_eR. For more information, ask your doctor or pharmacist.

COMMITTED TO AFFORDABILITY

Option 1: BlinkRx E-pharmacy

Get ACCRUF_eR delivered straight to your door, at the lowest price possible. Scan the QR code below to learn more.



Need help with BlinkRx?

844-926-2480



Support Hours

Monday - Friday 8 a.m. - 9 p.m. Eastern
Saturday 9 a.m. - 5 p.m. Eastern.

Option 2: Patient Savings Copay Card

You may be eligible to receive ACCRUF_eR for \$0* at your local pharmacy.

There are two ways to get an ACCRUF_eR patient savings copay card:



- Scan QR code to check eligibility and enroll online.
- Text **"SAVE"** to **23218** to receive your copay card and refill reminders via text[†]

*Restrictions apply. Patients with federal or state prescription coverage, such as Medicare or Medicaid, are not eligible. See Eligibility Terms and Conditions at ACCRUF_eR.copaysavingsprogram.com for more details.

[†]Message and data rates may apply. Message frequency varies. Reply HELP for help or STOP to opt out. See our Mobile Terms and Conditions and Privacy Policy at ACCRUF_eR.com.

IMPORTANT SAFETY INFORMATION (cont.)

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information about ACCRUF_eR enclosed or at ACCRUF_eR.com.

Patient Information
ACCRUFER® (ak-roo-fer)
(ferric maltol)
capsules

What is ACCRUFER?

ACCRUFER is a prescription medicine used in adults to treat low iron stores in your body. It is not known if ACCRUFER is safe and effective for use in children.

Do not take ACCRUFER if you:

- are allergic to ferric maltol or any of the ingredients in ACCRUFER. See the end of this leaflet for a complete list of ingredients in ACCRUFER.
- have any illness that causes you to store too much iron in your body or if you have a problem with how your body uses iron.
- are receiving repeated blood transfusions.

Before taking ACCRUFER, tell your healthcare provider about all your medical conditions, including if you:

- have inflammatory bowel disease (IBD).
- are pregnant or plan to become pregnant. It is not known if ACCRUFER will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ACCRUFER passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with ACCRUFER.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking ACCRUFER with certain other medicines may affect each other causing serious side effects. Some medicines may need to be taken at least 4 hours before or 4 hours after you have taken your ACCRUFER dose. Ask your healthcare provider for a list of these medicines if you are not sure if you take one of these medicines.

Especially tell your healthcare provider if you take:

- dimercaprol
 - other oral iron tablets or health supplements containing iron
- Ask your healthcare provider if you are not sure if you take one of these medicines.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ACCRUFER?

- Take ACCRUFER exactly as your healthcare provider tells you to.
- Take ACCRUFER 2 times a day on an empty stomach 1 hour before or 2 hours after meals.
- Swallow ACCRUFER capsules whole. Do not open, break, or chew ACCRUFER capsules.
- In case of accidental overdose, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ACCRUFER?

ACCRUFER may cause serious side effects, including:

- **Increased risk of inflammatory bowel disease (IBD) flare.** You should avoid taking ACCRUFER if you have inflammatory bowel disease (IBD) and are experiencing a flare.

- **Too much iron stored in your body (iron overload).** Your healthcare provider should check the iron level in your blood before you start and during treatment with ACCRUFER.
- **Risk of overdose in children due to accidental swallowing.** Accidental overdose of iron-containing products is a leading cause of death from poisoning in children under 6. Keep ACCRUFER in a safe place and out of the reach of children.

The most common side effects of ACCRUFER include:

- gas
- constipation
- stomach pain
- stomach area discomfort or bloating
- diarrhea
- discolored stools
- nausea or vomiting

These are not all the possible side effects of ACCRUFER.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ACCRUFER?

- Store ACCRUFER at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ACCRUFER and all medicines out of reach of children.

General information about the safe and effective use of ACCRUFER.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ACCRUFER for a condition for which it was not prescribed. Do not give ACCRUFER to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ACCRUFER that is written for health professionals.

What are the ingredients in ACCRUFER?

Active ingredient: ferric maltol

Inactive ingredients:

Capsule: colloidal anhydrous silica, crospovidone (Type A), lactose monohydrate, magnesium stearate, sodium lauryl sulfate

Capsule Shell: FD&C Blue No. 1 FD&C Red No. 40, FD&C Yellow 6, hypromellose, titanium dioxide.

Ink: ammonium hydroxide, ethanol, iron oxide black, propylene glycol

Distributed by Shield Therapeutics Inc, Suite 200, 100 Worcester Street, Wellesley Hills, MA, 02481

US Patents 7459569, 9248148, 9802973, 10179120

This Patient Information has been approved by the U.S. Food and Drug Administration.



ACCRUFer[®]
(ferric maltol) 30 mg capsules



ASK YOUR DOCTOR FOR IRON YOU'LL ACTUALLY TAKE.



Scan the QR code to learn more

References:

1. ACCRUFer full prescribing information. Shield Therapeutics. 2023.
2. DeLougery TG. Safety of oral and intravenous iron. *Acta Haematologica*. 2019;142(1): 8-12. doi:10.1159/000496966.
3. 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.
4. 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.
5. Data on file. Shield Therapeutics Inc. 2022.
6. 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.00000000000003146.
7. 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.
8. Miller JL. Iron deficiency anemia: a common and curable disease. *Cold Spring Harb Perspect Med*. 2013;3(7). doi:10.1101/cshperspect.a011866.
9. Cappellini MD, Musallam KM, Taher AT. Iron deficiency anemia revisited. *J Intern Med*. 2020;287(2): 153-170. doi:10.1111/joim.13004.
10. Ems T, et al. Biochemistry, Iron Absorption. *StatPearls*. 2021.
11. 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.
12. Howaldt S, Domènech E, Martínez 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.
13. 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.



ACCRUFer is a registered trademark of the Shield group of companies.
© 2024 Shield Therapeutics Inc. All rights reserved.
ACC-US-00334 (08/2024)