

# Ironemic

Lactoferrin 50 mg, GMP 5 mg and Elemental Iron (Ferrous Bisglycinate) 30 mg Tablets

*Exception* to the *Rule*



Patent Applied

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## ANEMIA:

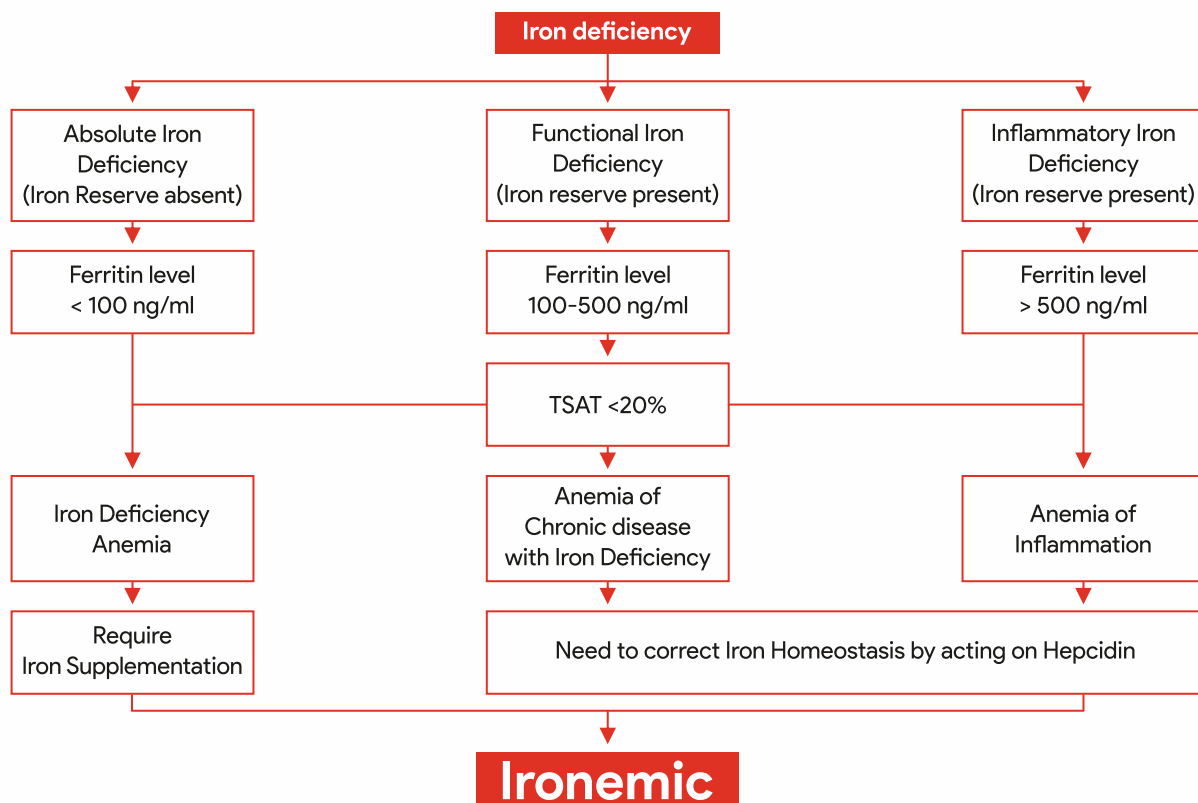
Anemia of chronic disease, also called the anemia of inflammation, is a condition that can be associated with many different underlying disorders including chronic illnesses such as cancer, certain infections, and autoimmune and inflammatory diseases.

- **1. Absolute or True Iron Deficiency:** Absolute iron deficiency is defined by severely reduced or absent storage iron in bone marrow, liver, and spleen.
- **2. Functional Iron Deficiency:** Functional iron deficiency is characterized by adequate iron stores but insufficient iron availability for incorporation into erythroid precursors.

Many different chronic conditions can cause inflammation that leads to Anemia, including

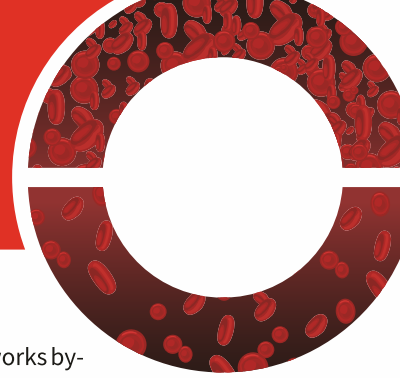
- Autoimmune diseases, such as rheumatoid arthritis or lupus
- Cancer
- Chronic infections, such as HIV/AIDS and tuberculosis
- Chronic Kidney Disease
- Inflammatory bowel disease (IBD), such as Crohn's disease or ulcerative colitis
- Other chronic diseases that involve inflammation, such as diabetes and heart failure, obesity

## PATHOPHYSIOLOGY:



**"Ironemic: Combination of Lactoferrin, GMP and Ferrous bisglycinate for any type of Iron deficiency anemia"**

# FUNCTIONAL IRON DEFICIENCY ANEMIA



## LACTOFERRIN - IRON HOMEOSTASIS REGULATOR:

Bovine lactoferrin (bLf), a glycoprotein is emerging as a natural substance effective in anaemia management. It works by-

- Pulling out stored iron from Enterocytes, Macrophages & Liver due to high binding affinity
- Downregulating Hepcidin release due to anti-inflammatory property
- Modulating Ferroportin Synthesis through down regulation of IL-6
- Restoring ferroportin-mediated iron export from cells to blood
- Addressing functional Iron deficiency through lactoferrin & as well reduce iron associated side effects

Taken together all the steps, bLf, showing a greater benefit and efficacy than the standard management, can be considered as a promising compound in treating anemia and AI (Anemia of Inflammation)

## FERROUS BISGLYCINATE: HIGHEST BIOAVAILABLE MOLECULE:

| Iron supplement             | Elemental iron | Bioavailable iron | Amount Absorbed (mg) |
|-----------------------------|----------------|-------------------|----------------------|
| Ferrous sulfate             | 33%            | 27%               | 9                    |
| Ferrous ascorbate           | 12%            | 40%               | 4.8                  |
| Ferrous fumarate            | 32%            | 28%               | 8.9                  |
| <b>Ferrous bisglycinate</b> | <b>19-21%</b>  | <b>91%</b>        | 17-19                |

## Efficacy and Safety of Oral Lactoferrin Supplementation in Combination with rHuEPO- $\beta$ for the Treatment of Anemia in Advanced Cancer Patients Undergoing Chemotherapy: Open-Label, Randomized Controlled Study

- Advanced-stage cancer patients often suffer from anemia that closely resembles the anemia of chronic inflammatory diseases characterized by specific changes in iron homeostasis and absorption.
- An open-label, randomized, prospective trial aimed at testing the efficacy and safety of treatment with oral lactoferrin versus i.v. iron, both combined with rHuEPO, for the treatment of anemia in a population of 148 advanced cancer patients undergoing chemotherapy.
- All patients received s.c. rHuEPO- $\beta$ , 30,000 UI once weekly for 12 weeks, and were randomly assigned to ferric gluconate (125 mg i.v. weekly) or lactoferrin (200 mg/day). Both arms showed a significant hemoglobin increase.
- In contrast, ferritin decreased in the lactoferrin arm whereas it increased in the i.v. iron arm.
- In conclusion, these results show similar efficacy for oral lactoferrin and for i.v. iron, combined with rHuEPO, for the treatment of anemia in advanced cancer patients undergoing chemotherapy.

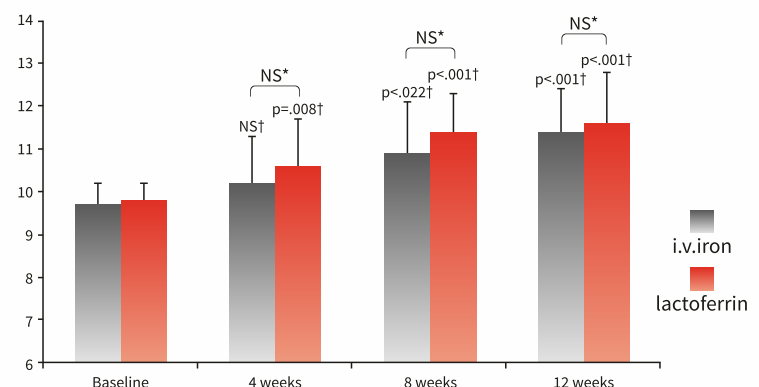


Fig: Hemoglobin (Hb) levels from baseline to the end of the study at week 12.

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## DESCRIPTION:

- **Ironemic** consists of Lactoferrin, Disodium Guanosine 5-Monophosphate and Ferrous bisglycinate.
- **Lactoferrin** is a non-haem iron-binding protein that is part of the transferrin protein family and differs from transferrin by its higher affinity for iron which is 300 times greater and its ability to retain iron at a pH lower than 4 such as exist. (E.g. in the gastrointestinal tract or inflammatory lesions).
- **Disodium Guanosine 5-Monophosphate (GMP)** is a salt of Guanosine 5-Monophosphate. GMP has been established as a promising candidate for inhibiting hepcidin-FPN interaction, thus promoting an effective iron-mediated erythropoiesis.
- **Ferrous bisglycinate** is a chelate that is used as a source of dietary iron. Forming a ring structure when reacting with glycine, ferrous bisglycinate acts as both a chelate and a nutritionally functional. It has been shown to be more effectively absorbed than other types of iron chelate in healthy people with different iron levels.

## INDICATION:

**Ironemic** is indicated for the management of Iron Deficiency Anemia and Anemia of Chronic Disease.

## MECHANISM OF ACTION:

Ironemic works by the following mechanisms -

1. Decreases Hepcidin levels by regulating the Ferroportin Hepcidin Axis
2. Increases iron efflux in the systemic circulation by Macrophage M1 to M2 phenotype conversion
3. Reduces ferritin bind iron stores
4. Reduces inflammatory pathways further affecting Hepcidin
5. Improves Ferroportin stabilization via GMP

## DOSAGE & ADMINISTRATION:

1-2 Tablets a day or as suggested by Healthcare Professional.




## Advantages of Ironemic:

- Effective increase of Hemoglobin and systemic Iron Levels
- Countering any adverse effect of inflammation arising due to Erythropoietin resistance
- Less likely to cause intestinal side effects such as nausea, constipation and bloating
- Restoration of Iron Homeostasis
- Ferrous bisglycinate has at least two-fold higher bioavailability/absorption compared to “conventional” iron salts, e.g., ferrous sulfate and ferrous fumarate.
- Useful in the treatment of both True/absolute iron deficiency anemia as well as Functional Iron deficiency anemia

Ref: Lepanto et al. Frontiers in Immunology, September 2018; Volume 9: Article 2123. 2) Macciò, Madeddu, Gramignano et al. The Oncologist 2010;15:894–90

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