

PROFESSIONAL INFORMATION
D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: [S0]

1. NAME OF THE MEDICINE
BIOGEN GENTLE IRON
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetarian capsule contains:		%NRV*
Iron (as Iron Bisglycinate)	24,00 mg	133
Folic acid (Vitamin B ₉)	500,00 µg	125

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetarian Capsules

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN GENTLE IRON, contains iron which contributes to the reduction of tiredness and fatigue by supporting the normal formation and function of red blood cells and haemoglobin, and the transport of oxygen in the body. Folic acid helps to form red blood cells.

4.2 Posology and method of administration

Adults and Children 14 years and older:

Take 1 (one) capsule daily before meals, or as recommended by your healthcare provider.

The safety and efficacy of BIOGEN GENTLE IRON in children younger than 14 years has not yet been established. Not allowed in children under 14 years.

Patients should not exceed the tolerable upper limit of 45 mg iron daily unless advised by a healthcare provider.

Patients are advised to take iron supplements on an empty stomach if possible. Taking iron supplements with food can decrease iron absorption by 40 % to 50 %.

4.3 Contraindications

- If you have a hypersensitivity to any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN GENTLE IRON.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a health care provider prior to use if symptoms worsen.
- Consult a healthcare provider prior to use if you are younger than 14 years.
- Caution is advised in patients with a history of peptic ulcer.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

No specific drug interaction studies have been performed on BIOGEN GENTLE IRON as a combination product. However the known interactions of ferrous bisglycinate and folic acid have been summarized.

Interactions with Medicines

- Iron reduces the absorption of bisphosphates and potentially affect bone density.
- Taking chloramphenicol with iron might reduce the response to iron therapy in iron deficiency anemia.
- Iron might decrease dolutegravir, levothyroxine, methylodopa, mycophenolate mofetil, and penicillamine levels by reducing its absorption.
- Iron might decrease the effectiveness of broad-spectrum antibiotics (quinolones or tetracyclines).
- Taking iron along with integrase inhibitors might decrease the levels and clinical effects of these medications.

Interactions with Diseases / Impairments

- Iron absorption is decreased in patients receiving haemodialysis.
- Iron overload is likely to occur in patients with hemoglobinopathies or other refractory anemias incorrectly diagnosed as iron deficiency anemia.
- Iron supplementation is associated with an increased risk of nosebleed in patients with HTT.
- Decreased stomach acidity may impair iron absorption.
- Supplemental iron absorption appears to be decreased in young women participating in physical training, as measured by serum ferritin levels.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN GENTLE IRON.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see section 4.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN GENTLE IRON does not adversely affect their performance.

4.8 Undesirable effects

Orally, BIOGEN GENTLE IRON is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Frequent: Abdominal pain, constipation, diarrhoea, gastrointestinal irritation, nausea, vomiting.

Description of selected adverse reactions

Severity of adverse effects listed in Section 4.8 b are typically dose dependent.

Paediatric Population

BIOGEN GENTLE IRON is not recommended for use in children under the age of 14 years.

Other special populations

No clinical data are available on the effects of BIOGEN GENTLE IRON on other special populations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Side effects listed in section 4.8 can be precipitated and / or be of increased severity. In the event of overdose, treatment should be symptomatic and supportive.

Acute overdosage, 60 mg / kg and more, can cause hematemesis and diarrhea, followed by cardiovascular, liver, or metabolic toxicity, and death. Long-term use of high doses of iron can cause hemosiderosis, that clinically resembles hemochromatosis.

Iron overdose during pregnancy in individuals with peak iron levels over 400 mcg/dL have been associated with organ failure, spontaneous abortion, preterm delivery, and maternal death.

Iron supplementation appears to be associated with greater adverse events in children. For example, in a clinical trial of 24,076 children, there was a 12 % increase in risk of hospitalization due to severe illness in children taking iron.

Treatment: There is insufficient reliable information available about the treatment of overdose with iron.

5. PHARMACOLOGICAL PROPERTIES
Mechanism of action:

Iron - Required for oxygen and carbon dioxide transport, functions in the electron transport chain as an electron carrier in cytochromes; plays a role in the Krebs cycle (energy release) and is an essential cofactor in neurotransmitter (dopamine, norepinephrine, and serotonin) synthesis.

Vitamin B₉ (Folic acid) - Helps the body metabolise proteins, form red blood cells and a factor in the maintenance of good health.

Pharmacodynamic effects:

Iron - Trace mineral, stores and transports iron (as myoglobin and hemoglobin) throughout the body.

Vitamin B₉ (Folic acid) - Water-soluble B vitamin, is a good factor in the maintenance of good health.

Pharmacokinetic properties

Iron

Absorption: Absorbed in the intestine (predominantly within the duodenum and lesser amounts in the jejunum).

Distribution: Iron is predominantly found in the hemoglobin of red blood cells. The remaining iron is stored in the bone marrow, liver, spleen, or muscle (myoglobin) as ferritin or hemosiderin.

Metabolism: Iron binds to the transport protein, transferrin, which in turn binds to the transferrin receptor complex. Once transferred into cells, iron can be incorporated into hemoglobin and myoglobin, stored as ferritin, or used to regulate cellular iron metabolism.

Excretion: Body iron is highly conserved. A small quantity of iron is excreted daily, mostly through the feces.

Vitamin B₉ (Folic acid)

Absorption: Synthetic Vitamin B₉ is almost 100 % bioavailable. Absorption occurs primarily in the duodenum and jejunum.

Distribution: Unknown.

Metabolism: Once absorbed, Vitamin B₉ is reduced to tetrahydrofolate which enters a methylation cycle. Tetrahydrofolate is converted to L-methylfolate.

Excretion: Predominantly excreted in the urine; however, it can also be present in the faeces.

Preclinical safety data

When used orally and appropriately in adults, BIOGEN GENTLE IRON is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Vegetarian capsules and maize starch.

6.2 Shelf Life

24 Months.

6.3 Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents

30 white to off white vegetarian capsules are available in a white 175 ml PET container sealed with a white Biogen embossed screw cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen
 23 Stag Road, Glen Austin, South Africa
 info@biogen.co.za
 www.biogen.co.za
 Tel: 0860 347243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

December 2022.