

**PROFESSIONAL INFORMATION**
**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 IRON PLUS capsules**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:		%NRV
Ferrous Succinate and Ferrous Gluconate (Providing elemental Iron)	130,70 mg 23,40 mg	130 %
Ascorbic Acid (Vitamin C)	150,00 µg	150 %
Folic Acid	500,00 mg	125 %
Riboflavin (Vitamin B <sub>2</sub> )	2,00 mg	154 %
Cyanocobalamin (Vitamin B12)	2,85 µg	116 %

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

Sugar Free

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Bovine Gelatine Capsules.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

BIOGEN IRON PLUS, contributes to normal formation of red blood cells and haemoglobin. It is required for normal oxygen transport and immune system function. The added vitamins contributes to tissue formation and iron absorption from foods

**4.2 Posology and method of administration**

*Adults and children >14 years:* Take 1 capsule daily, or as recommended by a healthcare provider. Take after a meal to help reduce the risk of gastric discomfort.

**4.3 Contraindications**

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

- Patients with peptic ulcer, Crohn's disease, or ulcerative colitis.
- Patients who suffer from disorders such as haemochromatosis or haemoglobinopathies.

**4.5 Interaction with other medicines and other forms of interaction**

- Patients must consult a healthcare practitioner if they are taking any other medicine (including complementary or traditional medicines).
- Patients should consult a healthcare practitioner prior to use if they are using any of the following medication: antacids; methyldopa; quinolone antibiotics; tetracycline antibiotics; thyroid agents; chloramphenicol; penicillamine.

**4.6 Fertility, pregnancy and lactation**

Safety in fertility, pregnancy and lactation has not been established.

**4.7 Effects on ability to drive and use machines**

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

**4.8 Undesirable effects**

Gastrointestinal disorders

*Frequent:* abdominal pain, constipation, diarrhoea, gastrointestinal irritation, nausea, vomiting.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization 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**

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. Treatment of overdose is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

**Category and class:** D 34.12 Multiple Substance Formulation. **Complementary Medicine: Health Supplement.**

**5.1 Pharmacodynamic properties**

**Iron** 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.

**Vitamin C** contributes to the absorption of iron. Vitamin B2 and B12 contribute to normal energy-yielding metabolism and the maintenance of good health.

**5.2 Pharmacokinetic properties**

Pharmacokinetic studies have not been conducted on BIOGEN IRON PLUS. The active ingredients are well known.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**

- Silicon dioxide, maize starch, and magnesium stearate.

**6.2 Incompatibilities**

Not applicable

**6.3 Shelf Life**

24 Months.

**6.4 Special precautions for storage**

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

**6.5 Nature and contents**

250 ml and 175 ml white PET container with a Biogen cap.

Pack size: 30, 60 capsules.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

**Biogen**

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Glen Austin, South Africa

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www.biogen.co.za

0860 347 243

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Will be allocated by SAHPRA upon registration.

**10. DATE OF REVISION OF THE TEXT**

November 2022