

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### HEMAGENICS IRON, 60 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU

- **HEMAGENICS IRON** is available without a doctor's prescription.
- Nevertheless, you still need to use **HEMAGENICS IRON** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **HEMAGENICS IRON** with any other person.
- Ask your pharmacist or healthcare practitioner if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **HEMAGENICS IRON** is and what it is used for.
- What you need to know before you take **HEMAGENICS IRON**.
- How to take **HEMAGENICS IRON**.
- Possible side effects.
- How to store **HEMAGENICS IRON**.
- Contents of the pack and other information.

#### WHAT HEMAGENICS IRON CONTAINS

Each one (1) tablet of HEMAGENICS IRON contains the following actives:

Glycine	100 mg
Iron (as Ferrous bis-glycinate)	24 mg
Vitamin B1 (as Thiamine mononitrate)	5 mg
Vitamin B6 (as Pyridoxal-5-phosphate)	5 mg
Copper (as cupric gluconate)	1 mg
Folate (as Calcium-L-methylfolate)	500 µg
Vitamin B12 (as Methylcobalamin)	100 µg

**Inactive Ingredients:** Dicalcium phosphate, microcrystalline cellulose, magnesium carbonate, magnesium salts of fatty acids, silicon dioxide.

**This product is suitable for non-GMO, gluten free and dairy free (Sugar Free)**

#### WHAT HEMAGENICS IRON IS USED FOR

**HEMAGENICS IRON** is a comprehensive supplement designed to support healthy red blood cell formation. Provides an excellent source of iron and other vital nutrients essential for red blood cell formation and maintenance.

#### BEFORE YOU TAKE HEMAGENICS IRON

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. Do not take **HEMAGENICS IRON** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare practitioner before taking this supplement.

This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.

#### PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has been established, consult with your healthcare practitioner before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare practitioner before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **HEMAGENICS IRON** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **HEMAGENICS IRON** may affect you.

#### TAKING OTHER MEDICINES WITH HEMAGENICS IRON

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner.

#### HOW TO TAKE HEMAGENICS IRON

Do not share medicines prescribed for you with any other person. Always take **HEMAGENICS IRON** exactly as described in this leaflet, or as your doctor, healthcare practitioner has instructed you. You should check with your doctor, pharmacist or healthcare practitioner if you are unsure.

#### Directions for use:

**Adult:** Take 1 tablet daily or as advised by your healthcare practitioner.

**Do not take more than the recommended dose.**

#### IF YOU TAKE MORE HEMAGENICS IRON THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.



#### IF YOU FORGET TO TAKE HEMAGENICS IRON

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**HEMAGENICS IRON** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare practitioner before use: Electrolyte imbalance, Antipsychotics, anticonvulsants, Metabolic Disorders, Kidney Disease, Hemochromatosis, Iron Overload Disorders, Haemolytic Anaemia, Wilson's Disease, Liver disease, Autoimmune disorders, Leber's Disease, Polycythaemia Vera. If you are taking the following medication, please consult with your healthcare practitioner before taking: Schizophrenia medications (Clozapine), CNS depressants, Antibiotics, penicillamine, anticonvulsants. Avoid drinking large amounts of alcohol. Heavy drinking can make it harder for your body to absorb methylcobalamin. If any of the following happens, stop using **HEMAGENICS IRON** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing, headaches and dizziness, rapid heart rate and flushing.

These are all very serious effects. If you have them, you may have had a serious reaction to **HEMAGENICS IRON**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare practitioner if they continue):

- Stomach discomfort (constipation/diarrhoea)

Not all side effects and interactions reported for **HEMAGENICS IRON** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare practitioner for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare practitioner.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare practitioner. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **HEMAGENICS IRON**.

#### STORAGE AND DISPOSING OF HEMAGENICS IRON

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

Do not use after the expiry date stated on the bottle.

Do not use **HEMAGENICS IRON** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF HEMAGENICS IRON

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### IDENTIFICATION OF HEMAGENICS IRON

Uncoated, light grey, round tablet.

#### REGISTRATION NUMBER - To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

14 October 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **B2**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

## HEMAGENICS IRON, 60 tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **HEMAGENICS IRON** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **HEMAGENICS IRON** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **HEMAGENICS IRON** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

**WAT IS IN HIERDIE INLIGTINGSBLAD**

- Wat **HEMAGENICS IRON** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **HEMAGENICS IRON** neem.
- Hoe om **HEMAGENICS IRON** te neem.
- Moontlike nuwe-effekte.
- Hoe om **HEMAGENICS IRON** te bêre.
- Inhoud van die pak en ander inligting

**WAT HEMAGENICS IRON BEVAT**

Elke een (1) tablet van **HEMAGENICS IRON** bevat die volgende aktiewe:

Glisien	100 mg
Yster (as ysterhoudende bis-glisinaat)	24 mg
Vitamiën B1 (as tiamienmononitraat)	5 mg
Vitamiën B6 (as Pyridoksaal-5-fosfaat)	5 mg
Koper (as koperglukonaat)	1 mg
Folaat (as kalsium-L-metielofolaat)	500 µg
Vitamiën B12 (as metielkobalamien)	100 µg

**Onaktiewe bestanddele:** Dikalsiumfosfaat, mikrokristallyn-sellulose, magnesiumkarbonaat, magnesiumsout van veture, silikondioksied.

**Hierdie produk is geskik vir nie-GGO, glutenvry en suiwelvry (suikervry)**

**WAT IS HEMAGENICS IRON EN WAARVOOR WORD DIT GEBRUIK**

**HEMAGENICS IRON** is 'n omvattende aanvulling wat ontwerp is om gesonde vorming van rooibloedselle te ondersteun. Verskaf 'n uitstekende bron van yster en ander nutriente wat noodsaaklik vir rooibloedsel vorming en instandhouding is.

**VOORDAT JY HEMAGENICS IRON NEEM**

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **HEMAGENICS IRON** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem. Hierdie medisyne is nie deur SAHPRa geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

**SWANGERSKAP EN BORSVOEDING**

Afhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

**BESTUUR EN GEBRUIK VAN MASHIENE**

Dit is nie altyd moontlik om te voorspel in watter mate **HEMAGENICS IRON** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **HEMAGENICS IRON** jou beïnvloed.

**NEEM ANDER MEDISYNE SAAM MET HEMAGENICS IRON**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne kan 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou mediese praktisyn te raadpleeg nie.

**HOE OM HEMAGENICS IRON TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **HEMAGENICS IRON** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**Aanwysings vir gebruik:**

**Volwasse:** Neem 1 tablet daaglik of soos aanbeveel deur jou gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER HEMAGENICS IRON NEEM AS WAT JY MOET**

– In die geval van oordosering, raadpleeg u dokter, apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGET OM HEMAGENICS IRON TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NUWE-EFFEKTE**

**HEMAGENICS IRON** kan nuwe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Elektrolietwanbalans, Antipsigotika, antikonvulsante, metaboliese afwykings, niërsiekte, hemochromatose, ysteroorladingsversteurings, hemoïtiese anemie, Wilson se siekte, Lewersiekte, outo-immunafwykings, Leber se siekte, polisitemie Vera. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Skisofrenie-medisyne (Clozapine), SSS-depressante, antibiotika, penisilamine, antikonvulsante. Vermoed die drink van groot hoeveelhede alkohol. Swaar drink kan dit moeiliker maak vir jou liggaam om metielkobalamien te absorbeer. As enige van die volgende gebeur, hou op om **HEMAGENICS IRON** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies - uitslag / jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling, hoofpyn en duiseligheid, vinnige hartklop en bloes.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **HEMAGENICS IRON** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Maagongemak (hardtygheid/diarree)

Nie alle nuwe-effekte en interaksies wat vir **HEMAGENICS IRON** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

**AANMELDING VAN NUWE-EFFEKTE**

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRa rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRa se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **HEMAGENICS IRON**.

**HOE OM HEMAGENICS IRON TE BÊRE**

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **HEMAGENICS IRON** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN HEMAGENICS IRON**

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakke.

**IDENTIFIKASIE VAN HEMAGENICS IRON**

Onbedekte, liggrys, ronde tablet.

**REGISTRASIE NUMMER** - Om deur SAHPRa toegeken te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING** Skandeer QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

14 Oktober 2024

**NAAM EN ADRES VAN REGISTRASIEHOUER**

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