

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

BRUNEL BASICS IRON PLUS tablets

Ferrous gluconate, ascorbic acid (vitamin C), nicotinamide (vitamin B₃), pyridoxine (vitamin B₆), riboflavin (vitamin B₂), thiamine (vitamin B₁), folic acid.

Sugar free.

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

D34.12 Multiple Substance Formulation

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

Read all of this leaflet carefully because it contains important information for you.

BRUNEL BASICS IRON PLUS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BRUNEL BASICS IRON PLUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What BRUNEL BASICS IRON PLUS is and what it is used for.
2. What you need to know before you take BRUNEL BASICS IRON PLUS.
3. How to take BRUNEL BASICS IRON PLUS.
4. Possible side effects.
5. How to store BRUNEL BASICS IRON PLUS.
6. Contents of the pack and other information.

1. What BRUNEL BASICS IRON PLUS is and what it is used for

BRUNEL BASICS IRON PLUS is a mineral supplement that is a source of iron. Iron is necessary in forming and maintaining healthy red blood cells in the body. Red blood cells transport oxygen, which is needed for energy. A lack of iron in the body may lead to tiredness and fatigue. BRUNEL BASICS IRON PLUS also contains vitamin C, which increases the amount of iron the body absorbs. Added B-vitamins (B₁, B₂, B₃, B₆) and folic acid also contribute to normal energy-yielding metabolism and maintaining good health.

2. What you need to know before you take BRUNEL BASICS IRON PLUS

Do not take BRUNEL BASICS IRON PLUS:

- if you are hypersensitive (allergic) to any of the ingredients in BRUNEL BASICS IRON PLUS (see **What BRUNEL BASICS IRON PLUS contains**).

Warnings and precautions

Take special care with BRUNEL BASICS IRON PLUS:

- if you suffer from conditions that affect your blood, such as Sideroblastic anaemia, haemolytic anaemia, hemochromatosis, thalassaemia or *Porphyria Cutanea Tarda*;
- if you suffer with stomach problems such as Crohn's disease, diverticulitis, intestinal stricture, gastric ulcers, gastroenteritis or ulcerative colitis.

Children and adolescents

BRUNEL BASICS IRON PLUS can be taken by children who are able to swallow tablets. Children under the age of 14, should take a maximum of 1 tablet per day.

Other medicines and BRUNEL BASICS IRON PLUS

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- BRUNEL BASICS IRON PLUS should not be taken at the same time as any other medication, as it may affect how these medications work in the body.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking BRUNEL BASICS IRON PLUS.

There is no evidence that BRUNEL BASICS IRON PLUS will cause harm to you or your baby during pregnancy or breastfeeding.

Driving and using machines

Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BRUNEL BASICS IRON PLUS affects you.

3. How to take BRUNEL BASICS IRON PLUS

Do not share medicines with any other person.

Always take BRUNEL BASICS IRON PLUS exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children 1 – 14 years of age: Take 1 tablet daily.

Adults and children older than 14 years of age: Take 2 tablets daily.

If you have the impression that the effect of BRUNEL BASICS IRON PLUS is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

BRUNEL BASICS IRON PLUS can be taken with or without food.

If you take more BRUNEL BASICS IRON PLUS than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining BRUNEL BASICS IRON PLUS with you so the doctor will know what you have taken.

4. Possible side effects

BRUNEL BASICS IRON PLUS can have side effects.

Not all side effects reported for BRUNEL BASICS IRON PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BRUNEL BASICS IRON PLUS, please consult your healthcare provider for advice.

If any of the following happens, stop taking BRUNEL BASICS IRON PLUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BRUNEL BASICS IRON PLUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- angina;
- changes in the way your heart beats, for example, if you notice it beating faster;
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- mild flushing (your skin may turn red);
- allergic reactions;
- constipation;
- diarrhoea;
- nausea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online **under SAHPRA’s publications**: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BRUNEL BASICS IRON PLUS.

5. How to store BRUNEL BASICS IRON PLUS

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom due to high humidity.
- Do not use after the expiry date printed on the label.
- Store in the original packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BRUNEL BASICS IRON PLUS contains

Each tablet contains:

The active substances are:

| | |
|--|----------|
| Ferrous gluconate | 58 mg |
| providing iron (elemental) | 7 mg |
| Ascorbic acid (Vitamin C) | 175 mg |
| Nicotinamide (Vitamin B ₃) | 10 mg |
| Pyridoxine hydrochloride | 0,761 mg |
| providing pyridoxine (Vitamin B ₆) | 0,626 mg |
| Riboflavin (Vitamin B ₂) | 0,7 mg |
| Thiamine hydrochloride | 0,578 mg |
| providing thiamine (Vitamin B ₁) | 0,455 mg |
| Folic acid | 0,2 mg |

The other ingredients are dicalcium phosphate (E 341), magnesium stearate (E 572) and Nutrafinish red coating.

Contains sweetener: Each tablet contains 171 mg sorbitol (E 420).

What BRUNEL BASICS IRON PLUS looks like and contents of the pack

90 medium sized, round, reddish-pink tablets in a black plastic container with a silica gel sachet.

Holder of certificate of registration

Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
0157
info@brunel.co.za

This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

The Professional Information for BRUNEL BASICS IRON PLUS is available on

<https://www.brunel.co.za/professional-information/> or can be requested from the contact details above.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

BRUNEL BASICS IRON PLUS tablette

Ysterglukonaat, askorbiensuur (vitamien C), nikotinamied (vitamien B₃), piridoksien (vitamien B₆), riboflaviën (vitamien B₂), tiamien (vitamien B₁), foliensuur.
Suikervry.

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

D34.12 Formule met verskeie bestanddele

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

BRUNEL BASICS IRON PLUS is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy BRUNEL BASICS IRON PLUS versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat BRUNEL BASICS IRON PLUS is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy BRUNEL BASICS IRON PLUS neem.
3. Hoe om BRUNEL BASICS IRON PLUS te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BRUNEL BASICS IRON PLUS te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat BRUNEL BASICS IRON PLUS is, en waarvoor dit gebruik word

BRUNEL BASICS IRON PLUS is 'n mineraalaanvulling wat 'n bron van yster is. Yster is noodsaaklik om gesonde rooibloedselle in die liggaam te vorm en in stand te hou. Rooibloedselle vervoer suurstof, wat nodig is vir energie. 'n Gebrek aan yster in die liggaam kan lei tot moegheid. BRUNEL BASICS IRON PLUS bevat ook vitamien C, wat die hoeveelheid yster wat die liggaam opneem, verhoog. Bygevoegde B-vitamienes (B₁, B₂, B₃, B₆) en foliensuur dra ook by tot normale energie-oplewende metabolisme en die instandhouding van goeie gesondheid.

2. Wat jy moet weet voordat jy BRUNEL BASICS IRON PLUS neem

Moet nie BRUNEL BASICS IRON PLUS neem:

- indien jy hipersensitief (allergies) is vir enige van die bestanddele van BRUNEL BASICS IRON PLUS nie (sien **Wat BRUNEL BASICS IRON PLUS bevat**).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met BRUNEL BASICS IRON PLUS:

- indien jy aan enige siektetoestande ly wat jou bloed beïnvloed, soos Sideroblastiese anemie, hemolitiese anemie, hemochromatose, talassemie of *Porphyria Cutanea Tarda*;
- indien jy aan enige maagprobleme soos Crohn se siekte, divertikulitis, intestinale vernouing, maagsere, gastro-enteritis of ulseratiewe kolitis ly.

Kinders en adolessente

BRUNEL BASICS IRON PLUS kan deur kinders geneem word wat tablette kan sluk. Kinders onder die ouderdom van 14 moet 'n maksimum van 1 tablet per dag neem.

Ander medisyne en BRUNEL BASICS IRON PLUS

- Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
- BRUNEL BASICS IRON PLUS moet nie op dieselfde tyd as enige ander medikasie geneem word nie, aangesien dit die manier waarop die medikasies in die liggaam werk, kan beïnvloed.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy BRUNEL BASICS IRON PLUS neem.

Daar is geen bewyse dat BRUNEL BASICS IRON PLUS skade aan jou of jou baba sal rig tydens swangerskap of borsvoeding nie.

Bestuur en die gebruik van masjiene

Dit is nie vasgestel of BRUNEL BASICS IRON PLUS veilig en doeltreffend is tydens bestuur en die gebruik van masjiene nie. Moet nie 'n voertuig bestuur, masjiene hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe BRUNEL BASICS IRON PLUS jou affekteer nie.

3. Hoe om BRUNEL BASICS IRON PLUS te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem BRUNEL BASICS IRON PLUS altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Kinders 1 – 14-jarige ouderdom: Neem 1 tablet daagliks.

Volwassenes en kinders ouer as 14 jaar oud: Neem 2 tablette daagliks.

Indien jy die indruk kry dat die uitwerking van BRUNEL BASICS IRON PLUS te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

BRUNEL BASICS IRON PLUS kan met of sonder kos geneem word.

As jy meer BRUNEL BASICS IRON PLUS neem as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BRUNEL BASICS IRON PLUS saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike nuwe-effekte

BRUNEL BASICS IRON PLUS kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir BRUNEL BASICS IRON PLUS gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy BRUNEL BASICS IRON PLUS neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om BRUNEL BASICS IRON PLUS te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op BRUNEL BASICS IRON PLUS gehad het. Dringende mediese bystand of hospitalisasie mag nodig wees.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling in jou naaste hospitaal as jy een van die volgende opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy voel dat dit vinniger klop;
- asemhalingsprobleme.

Hierdie is almal ernstige nuwe-effekte. Jy kan dalk dringende mediese bystand benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Neuwe-effekte wat minder gereeld voorkom:

- matige blosing (jou vel kan rooi word);
- allergiese reaksies;
- hardlywigheid;
- diarree;
- naarheid.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn by **SAHPRA se publikasies** beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van BRUNEL BASICS IRON PLUS te verskaf.

5. Hoe om BRUNEL BASICS IRON PLUS te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in 'n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie.
- Moet nie gebruik word na die vervaldatum soos aangedui op die etiket nie.
- Bêre in die oorspronklike verpakking.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat BRUNEL BASICS IRON PLUS bevat

Elke tablet bevat:

Die aktiewe bestanddele is:

| | |
|--|----------|
| Ysterglukonaat | 58 mg |
| lewer yster (elementaal) | 7 mg |
| Askorbiensuur (Vitamiën C) | 175 mg |
| Nikotinamied (Vitamiën B ₃) | 10 mg |
| Piridoksien hidrochloried | 0,761 mg |
| lewer piridoksien (Vitamiën B ₆) | 0,626 mg |
| Riboflaviën (Vitamiën B ₂) | 0,7 mg |
| Tiamien hidrochloried | 0,578 mg |
| lewer tiamien (Vitamiën B ₁) | 0,455 mg |
| Foliensuur | 0,2 mg |

Die ander bestanddele is dikalsiumfosfaat (E 341), magnesiumstearaat (E 572) en Nutrafinish rooi deklaag.

Bevat versoeter: Elke tablet bevat 171 mg sorbitol (E 420).

Hoe BRUNEL BASICS IRON PLUS lyk en inhoud van die verpakking

90 medium grootte, ronde rooi-pienk tablette in 'n swart houër met 'n silikajeluitdroogmiddel.

Houer van die registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

info@brunel.co.za

Hierdie inligtingsblad is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir BRUNEL BASICS IRON PLUS is beskikbaar by <https://www.brunel.co.za/professional-information/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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