Appendix I – Drug Company Patient Information Leaflet

VITAFORCE FEROVITE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
Unscheduled

PROPRIETARY NAME AND DOSAGE FORM
The name of your medicine is VITAFORCE FEROVITE.
VITAFORCE FEROVITE is available in a tablet dosage form.
The VITAFORCE FEROVITE contains two active ingredients; ferrous fumarate and folic acid.

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU
VITAFORCE FEROVITE is available without a doctor's prescription, for you to treat a mild illness.
Nevertheless, you still need to use VITAFORCE FEROVITE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VITAFORCE FEROVITE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT VITAFORCE FEROVITE CONTAINS
Each tablet contains the following active ingredients:

Ferrous Fumarate	
(providing 65,0 mg elemental Iron)	200,0 mg
Folic Acid	100,0 µg

The tablet also contains other ingredients (inactive ingredients): microcrystalline cellulose, povidone, croscarmellose sodium and magnesium stearate.

WHAT VITAFORCE FEROVITE IS USED FOR
VITAFORCE FEROVITE is an iron and folic acid nutritional supplement to help overcome dietary deficiencies particularly during pregnancy. It is used for the prevention of iron deficiency and folate-deficient megaloblastic anaemia in pregnancy. Anaemia means that there is lower than normal number of red blood cells or quantity of haemoglobin in the blood. Iron-deficiency anaemia results from lack of iron, which is necessary for the production of haemoglobin. Folate-deficient megaloblastic anaemia results from deficiency of folate (folic acid).

BEFORE YOU TAKE VITAFORCE FEROVITE
Do not take VITAFORCE FEROVITE if:
If you are hypersensitive (allergic) to (ferrous fumarate or iron salts and folic acid or any of the other ingredients. VITAFORCE FEROVITE is not used for prophylaxis of megaloblastic anaemia associated with vitamin B_{12} deficiency. If you have haemochromatosis (a genetic disorder causing an excess iron in the body), chronic haemolysis (the abnormal breakdown of red blood cells) and frequent transfusions do not use VITAFORCE FEROVITE. If you have problems with the incorporation of iron (sickle cell anaemia - disorder caused by the presence of an abnormal form of haemoglobin), anaemia associated with lead poisoning, thalassemia (hereditary disorder in which the blood makes an abnormal form of haemoglobin), do not use VITAFORCE FEROVITE. If you have severe kidney and liver dysfunction, do not use VITAFORCE FEROVITE.
VITAFORCE FEROVITE should not be used together with iron administered as an injection. This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SPECIAL CARE SHOULD BE TAKEN WITH VITAFORCE FEROVITE
Do not exceed the stated dose. Prolonged administration in excess of the recommended dose may result in iron overload and other side effects. Iron overloading and toxicity may occur in patients receiving both VITAFORCE FEROVITE and iron administered by injection. Care should be taken when VITAFORCE FEROVITE is used by patients with active gastrointestinal inflammation (e.g. gastritis – inflammation of the stomach lining, gastric and duodenal ulcer – ulcer in the stomach and duodenum, Crohn's disease- condition in which parts of the gastrointestinal tract become inflamed, thickened, ulcerated, and scarred or ulcerative colitis – inflammation and ulceration of the colon. Benzidine or similar tests for detection of blood in the faeces may yield false positives. VITAFORCE FEROVITE must be discontinued for 3 days prior to the planned performance of the test. A minority of pregnant women are not protected by physiological doses of folic acid

TAKING VITAFORCE FEROVITE WITH FOOD AND DRINK
Take VITAFORCE FEROVITE on an empty stomach to enhance iron absorption. The concurrent intake of products with a high content of vegetable constituents, phosphates and tannins limits the absorption of iron.
Fish and food with a high content of ascorbic acid and fruit promotes iron absorption.

PREGNANCY AND BREASTFEEDING
VITAFORCE FEROVITE is used in the prevention of iron deficient and folate deficient megaloblastic anaemia in pregnancy. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

DRIVING AND USING MACHINERY
VITAFORCE FEROVITE does not interfere with your ability to drive and use machines.

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF VITAFORCE FEROVITE
VITAFORCE FEROVITE tablets are sugar-free.

TAKING OTHER MEDICINES WITH VITAFORCE FEROVITE
Always tell your healthcare provider if you are taking any other medicines (This includes complementary or traditional medicines).
Examples of medicines that may interact with VITAFORCE FEROVITE tablets include:
Tetracyclines, administer VITAFORCE FEROVITE at least three hours before or two hours after the tetracycline.
Medicine containing calcium and magnesium bicarbonates (including antacids) as well as carbonates oxalates and phosphates and trientine. These medicines impair iron absorption by formation of insoluble complexes.
Cholestyramine prevents intestinal absorption of iron.
Avoid taking chloramphenicol and VITAFORCE FEROVITE at the same time; take them three hours apart from each other.
VITAFORCE FEROVITE can decrease the absorption of other medicines including; bisphosphonates, fluoroquinones, levodopa, methyldopa, carbidopa, entacapone, penicillamine and mycophenolate.
Sulphonamides, anticonvulsants and barbiturates impair the absorption of folic acid. Administration of VITAFORCE FEROVITE with food may impair the absorption of iron.
Tetracyclines, administer VITAFORCE FEROVITE at least three hours before or two hours after the tetracycline.

HOW TO TAKE VITAFORCE FEROVITE
Do not share medicines prescribed for you with any other person.
Always take VITAFORCE FEROVITE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Adults: 18 years and older
Take 1 to 3 tablets daily or as directed by your health care provider.
Take the tablets on an empty stomach to enhance iron absorption.
Your doctor will tell you how long your treatment will last. If you have the impression that the effect of VITAFORCE FEROVITE is too strong or too weak, tell your doctor or pharmacist.

IF YOU TAKE MORE VITAFORCE FEROVITE THAN YOU SHOULD
The initial symptoms you may experience include: diarrhoea, nausea and vomiting, abdominal cramping, vomiting of blood, rectal bleeding, lack of energy and enthusiasm (lethargy) and general or specific failure of the circulation (circulatory collapse). Excess glucose in the bloodstream (hyperglycaemia) and metabolic acidosis (when the body produces too much acid or when the kidneys are not removing enough acid from the body) may occur.
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE A DOSE OF VITAFORCE FEROVITE
Do not take a double dose to make up for forgotten individual doses.
Continue taking the tablets as directed on the label.
Contact your healthcare provider for further advice.

POSSIBLE SIDE EFFECTS
VITAFORCE FEROVITE can have side effects.
Stop taking VITAFORCE FEROVITE immediately and check with your doctor immediately or go to the casualty department at your nearest hospital: If you experience, rapid shallow breathing, dizziness or light-headedness, fainting, lack of concentration, cold, clammy, pale skin, fatigue, vomiting, abdominal cramping, vomiting of blood, rectal bleeding, lack of energy and enthusiasm (lethargy) and general or specific failure of the circulation (circulatory collapse).
Other side effects may occur. However check with your doctor if any of the following side effects continue or are bothersome:
Discoloured faeces, abdominal bloating, upper abdominal pain, constipation, diarrhoea, nausea and allergic dermatitis.
Not all side effects reported for VITAFORCE FEROVITE are included in this leaflet. Should your general state of health worsens while taking VITAFORCE FEROVITE, please consult your doctor, pharmacist or other healthcare provider for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF VITAFORCE FEROVITE
Store at or below 25 °C.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the container tightly closed.
Protect from light.
Protect from moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the label.
Do not use VITAFORCE FEROVITE if you notice visible signs of deterioration.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF VITAFORCE FEROVITE
White plastic container with a white plastic screw cap containing 28, 56, 84, 100, 500 or 1000 tablets

IDENTIFICATION OF VITAFORCE FEROVITE
Light brown speckled round tablet

REGISTRATION NUMBER
TBA

DATE OF REGISTRATION
TBA

PROFESSIONAL INFORMATION
For further information refer to the Professional Information of the product.

NAME AND ADDRESS OF REGISTRATION HOLDER
Ascendis Supply Chain (Pty) Ltd
1 Carey Street
Wynberg, Sandton
JOHANNESBURG
2090
+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
TBA

VITAFORCE FEROVITE

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS
Ongeskeduleer

HANDELSNAAM EN DOSEERVORM
Die naam van jou medikasie is VITAFORCE FEROVITE.
VITAFORCE FEROVITE is beskikbaar in 'n tablet doseervorm.
Die VITAFORCE FEROVITE bevat twee aktiewe bestanddele; ysterfumeraat en foliensuur.

LEES DIE HELE INLIGTINGSBLAADJIE NOUKEURIG DEUR, DIT BEVAT BELANGRIKE INLIGTING VIR JOU
VITAFORCE FEROVITE is beskikbaar sonder 'n dokters voorskrif, vir jou om matige siekte te behandel.
Ongeag, jy moet steeds VITAFORCE FEROVITE versigtig gebruik om die beste resultate te verkry.

- Hou hierdie pamflet. Dit mag dalk nodig wees om dit weer te lees.
- Moet nie VITAFORCE FEROVITE met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Raadpleeg 'n dokter as jou simptome versleg of nie verbeter nie.

WAT VITAFORCE FEROVITE BEVAT
Elke tablet bevat die volgende aktiewe bestanddele:

Yster Fumeraat	
(verskaf 65,0 mg elementale Yster)	200,0 mg
Foliensuur	100,0 µg

Die tablet bevat ook ander bestanddele:
(onaktiewe bestanddele): mikrokristallyn sellulose, povidoon, kroskarmellose natrium en magnesium stearaat.

WAARVOOR VITAFORCE FEROVITE GEBRUIK WORD
VITAFORCE FEROVITE is 'n yster en foliensuur voedingsaanvulling wat help om dieetkekorte, verral tydens swangerskap, te behandel. Dit word gebruik vir die voorkoming van yster en folaat-tekort megaloblastiese anemie in swangerskap. Anemie beteken dat daar laer as die normale hoeveelheid rooibloedselle of hoeveelheid hemoglobien in die bloed is. Yster-tekort anemie kom voor as gevolg van 'n tekort aan yster, wat nodig is vir die produksie van hemoglobien. Folaat-tekort megaloblastiese anemie kom voor as gevolg van 'n tekort aan folaat (foliensuur).

VOORDAT VITAFORCE FEROVITE GEBRUIK WORD
Moet nie VITAFORCE FEROVITE neem as:
Jy hipersensitief (allergies) is vir yster fumeraat, yster-soute en foliensuur of enige van die ander bestanddele. VITAFORCE FEROVITE word nie gebruik vir die profilakse van megaloblastiese anemie wat geassosieer word met vitamien B_{12} tekort nie. As jy aan hemochromatosis ('n genetiese afwyking wat 'n oormatige hoeveelheid yster in die liggaam veroorsaak) en kroniese hemolise (die abnormale afbraak van rooibloedselle) ly of gereelde bloedoortappings kry, moet nie VITAFORCE FEROVITE gebruik nie. As jy probleme het met die insluiting van yster (sekelsel-anemie, afwyking wat veroorsaak word deur die teenwoordigheid van 'n abnormale vorm van hemoglobien), anemie geassosieer met lood-vergiftiging of tallassemia (oorerflike afwyking waar bloed 'n abnormale vorm van hemoglobien produseer) moet nie VITAFORCE FEROVITE gebruik nie. As jy ernstige nier -en lewer inkorting het, moet nie VITAFORCE FEROVITE gebruik nie. VITAFORCE FEROVITE moet nie tesamelik gebruik word moet yster wat deur inspuiting toegedien word nie. Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

NEEM SPESIALE SORG MET VITAFORCE FEROVITE
Moet nie die gestelde dosis oorskry nie. Verlengde toediening in oormaat, meer as die gestelde dosis mag in yster-oorlading en ander newe-effekte resulteer. *Yster-oorlading en toksisiteit mag voorkom in pasiënte wat beide VITAFORCE FEROVITE en yster wat deur inspuiting toegedien word, gebruik. Sorg moet geneem word wanneer VITAFORCE FEROVITE gebruik deur pasiënte met aktiewe gastrointestinale inflammasie (bv gastritis - inflammasie van die maagslymvlies, gastriese-en duodenale ulsers - ulsers in die maag en duodenum, Crohn se siekte - toestand waar gedeeltes van die spysverteringskaal inflammasie ontwikkel, verdik of ulseratief raak of littekens ontwikkel en ulseratiewe kolitis - inflammasie en ulserasie van die kolon. Bensidien of soortgelyke toetse vir die teenwoordigheid van bloed in feses, mag vals positiewe resultate lewer. VITAFORCE FEROVITE moet onttrek word 3 dae voor die beplande uitvoering van die toets. 'n Minderheid van swanger vroue word nie beskerm deur fisiologiese dosisse van foliensuur nie.*

NEEM VAN VITAFORCE FEROVITE MET KOS EN DRANK
Neem VITAFORCE FEROVITE op 'n leë maag op yster absorpsie te verbeter. Die gelyktydige inname van produkte met 'n hoë inhoud van groente-bestanddele, fosfate en tannoïede, beperk die absorpsie van yster.
Vis, voedsel met 'n hoë askorbiensuur inhoud en vrugte bevorder die absorpsie van yster.

SWANGERSKAP EN BORSVOEDING
VITAFORCE FEROVITE word gebruik in die voorkoming van yster en folaat-tekort megaloblastiese anemie in swangerskap.
Indien jy swanger is of borsvoed, raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies voor die gebruik van hierdie medikasie.

DIE BESTUUR EN GEBRUIK VAN MASJINERIE
VITAFORCE FEROVITE belemmer nie jou vermoë om te bestuur of masjinerie te gebruik nie.

BELANGRIKE INLIGTING IN VERBAND MET SOMMIGE VAN DIE BESTANDDELE IN VITAFORCE FEROVITE
VITAFORCE FEROVITE tablette is suiker-vry.

AS JY ANDER MEDISYNE SAAM MET VITAFORCE FEROVITE NEEM
Raadpleeg altyd jou gesondheidsorgpraktisyn as jy enige ander medikasie gebruik (Dit sluit komplimentêre en tradisionele medikasie in).

Voorbeelde van medikasie wat interaksies met VITAFORCE FEROVITE kan hê sluit in:
Tetrasikliene, dien VITAFORCE FEROVITE ten minste drie ure voor of twee ure na tetrasikliene toe.
Medikasie wat kalsium en magnesium bikarbonaat bevat (insluitend teensuurmiddels) sowel as karbonate, oksalate, fostate en trientiene.
Hierdie medikasie kan ysterabsorpsie belemmer deur formulering van onoplosbare komplekse.
Kolestiramien voorkom die intenstinale absorpsie van yster.
Vermy die gelyktydige gebruik van chlooramfenikol en VITAFORCE FEROVITE; neem hulle drie ure weg van mekaar af.
VITAFORCE FEROVITE kan die absorpsie van ander medikasie verminder insluitend; botostonate, fluorokinolone, levodopa, metieldopa, karbidopa, entakapoon, pensiellamiene en mikofenoloaat.
Sulfoonamiede, antikonvulsante en barbiturate, inhibeer die absorpsie van foliensuur. Gelyktydige toediening van VITAFORCE FEROVITE met voedsel mag die absorpsie van yster inhibeer.
Tetrasikliene, dien VITAFORCE FEROVITE ten minste drie ure voor of twee ure na tetrasikliene toe.

HOE OM VITAFORCE FEROVITE TE GEBRUIK

Moenie jou medisyne met enige iemand anders deel nie.
Neem VITAFORCE FEROVITE altyd presies soos aanbeveel. Bevestig met jou dokter of apteker indien jy onseker is.
Volwassenes 18 jaar en ouer
Neem 1 tot 3 tablette daagliks of soos aanbeveel deur 'n gesondheidsorgpraktisyn.
Neem die tablette op 'n leë maag om yster absorpsie te verbeter.
Jou dokter sal jou adviseer oor hoe lank jou terapie sal duur. As jy onder die indruk is dat die effek van VITAFORCE FEROVITE te sterk of te swak is, raadpleeg jou dokter of apteker.

INDIEN JY MEER VITAFORCE FEROVITE GEBRUIK AS WAT JY BEHOORT

Die aanvanklike simptome wat jy mag ervaar sluit in: diarree, naarheid en braking, abdominale krampe, braak van bloed, rektale bloeding, tekort aan energie en entoesiasme (letargie) en algemene of spesifieke mislukking van sirkulasie (sirkulatoriese ineenstorting).Oormatige glukose in die bloedstroom (hiperglisemie) en metaboliese asidose (wanneer die liggaam te veel suur produseer of wanneer die niere nie genoeg suur uit die liggaam verwyder nie), mag voorkom.
In die geval van 'n oordosis, raadpleeg jou dokter of apteker. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

INDIEN JY VERGEET HET OM VITAFORCE FEROVITE TE NEEM

Moenie 'n dubbele dosis neem om vir oorgeslane dosisse te vergoed nie.
Hou aan om die tablette te neem soos aangedui word op die etiket.
Kontak jou gesondheidsorgpraktisyn vir verdere advies.

MOONTLIKE NEWE-EFFEKTE

VITAFORCE FEROVITE kan moontlik newe-effekte veroorsaak.
Staak die gebruik van VITAFORCE FEROVITE onmiddelik en raadpleeg jou dokter of gaan na die ongevalle departement van die naaste hospitaal: As jy vinnige en oppervlakkige asemhaling, duiseligheid of lighoofdigheid, floute, tekort aan konsentrasie, koue, klam en bleek vel, moegheid, braking, abdominale krampe, braking van bloed, rektale bloeding, tekort aan energie en entoesiasme (letargie) en algemene of spesifieke ineenstorting van sirkulasie (sirkulatoriese ineenstorting).
Ander newe-effekte mag voorkom. Raadpleeg egter jou dokter as enige van die newe-effekte aanhou of lastig raak: Verkleurde feses, abdominale opgeblasenheid, boonste abdominale pyn, konstipasie, diarree, naarheid en allergiese dermatitis.
Nie alle newe-effekte wat vir hierdie medisyne aangemeld is word in hierdie voubiljet genoem nie. Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind terwyl jy hierdie medikasie gebruik, moet jy asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn raadpleeg.
Indien jy enige newe-effekte waarneem wat nie in hierdie voubiljet genoem word nie, moet jy jou dokter of apteker daarvan vertel.

BERGING EN WEGDOEN VAN VITAFORCE FEROVITE

Bewaar teen of benede 25 °C.
Bewaar alle medikasie buite bereik van kinders.
Bewaar in die oorspronklike houer.
Maak die houer dig toe.
Beskerm teen lig.
Beskerm teen vog.
Moet nie in die badkamer stoor nie.
Moet nie gebruik na die vervaldatum wat op die etiket aangedui is nie.
Moenie VITAFORCE FEROVITE gebruik indien jy enige sigbare tekens van produkafbraak opmerk nie.
Bewaar die houer in die kartonverpakking.
Bewaar in die oorspronklike houer.

AANBIEDING VAN *VITAFORCE FEROVITE*

Wit, plastiek houer *met 'n wit pastiek skroefprop wat 28, 56, 84, 100,* 500 of 1000 tablette *bevat.*

IDENTIFIKASIE VAN VITAFORCE FEROVITE

Ligbruin, gespikkelde, ronde tablet

REGISTRASIENOMMER

TBA

DATUM VAN REGISTRASIE

TBA

PROFESSIONELE INLIGTING

Verwys na die voubiljet met professionele inligting vir meer inligting.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING

TBA

VITAFORCE FEROVITE

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

VITAFORCE FEROVITE, tablet

COMPOSITION

Each tablet contains:

Ferrous Fumarate (providing 65,0 mg elemental Iron)	200,0 mg
Folic Acid	100,0 µg

Inactive ingredients: Microcrystalline cellulose, povidone, croscarmellose sodium and magnesium stearate.
Sugar free

PHARMACOLOGICAL CLASSIFICATION

A 8.3 Erythropietics (haematinics)

PHARMACOLOGICAL ACTION

Folic acid in the body is reduced to tetra hydrofolate, a co-enzyme for various metabolic processes. Ferrous fumarate is a source of iron for iron deficiency anaemia.

INDICATIONS

VITAFORCE FEROVITE is an iron and folic acid nutritional supplement to help overcome dietary deficiencies particularly during pregnancy. It is indicated for the prophylaxis of iron deficiency and folate-deficient megaloblastic anaemia in pregnancy.
VITAFORCE FEROVITE is not intended to the treatment of megaloblastic anaemia in pregnancy, only for its prevention and it's not indicated for the prevention or treatment of anaemia in men, non-pregnant women, or children.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients. Megaloblastic anaemia associated with vitamin B_{12} deficiency. Iron overload (haemochromatosis, chronic haemolysis, frequent transfusions). Problems with incorporation of iron (sickle cell anaemia, anaemia associated with lead poisoning, thalassemia). Severe renal and hepatic dysfunction. Do not use in conjunction with parenteral iron formulations.

WARNINGS AND SPECIAL PRECAUTIONS

Do not exceed the stated dose. Prolonged administration in excess of the recommended dose may result in iron overload and other adverse reactions. Iron overloading and toxicity may occur in patients receiving both VITAFORCE FEROVITE and parenteral administration of iron (see CONTRAINDICATIONS).
Gastrointestinal Inflammation: Care should be taken when administering VITAFORCE FEROVITE to patients with active gastrointestinal inflammation (e.g. gastritis, gastric and duodenal ulcer, Crohn's disease or ulcerative colitis).
Stool darkening: VITAFORCE FEROVITE may lead to darkening of the stool, giving the appearance of a tarry stool.
Investigation: Benzidine or similar tests for detection of faecal occult blood may yield false positives. VITAFORCE FEROVITE must be discontinued for 3 days prior to the planned performance of the test.
A minority of pregnant women are not protected by physiological doses of folic acid.
The development of anaemia despite prophylaxis with VITAFORCE FEROVITE calls for investigation and appropriate therapy.
Ability to perform tasks that require judgement, motor or cognitive skills: No effect on the ability to drive and use of machines was observed.
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

INTERACTIONS

The absorption of iron salts and tetracyclines is diminished when taken concomitantly. If treatment with both VITAFORCE FEROVITE and a tetracycline is required, the iron salt should be administered at least three hours before or two hours after the tetracycline. Medicine containing calcium and magnesium bicarbonates (including antacids) as well as carbonates oxalates and phosphates and trientine, impair iron absorption by formation of insoluble complexes.
Cholestyramine inhibits intestinal absorption of iron.
The concomitant administration of chloramphenicol may delay the therapeutic action of VITAFORCE FEROVITE.
VITAFORCE FEROVITE can decrease the absorption of other medicines including; bisphosphonates, fluoroquinones, levodopa, methyldopa, carbidopa, entacapone, penicillamine and mycophenolate.
Sulphonamides, anticonvulsants and barbiturates impair the absorption of folic acid. Administration of VITAFORCE FEROVITE with food may impair the absorption of iron.
The concurrent intake of products with a high content of vegetable constituents, phosphates and tannins limits the absorptions limits the absorption of iron, while fish and food with a high content of ascorbic acid and fruit have the opposite effect.

HUMAN REPRODUCTION

PREGNANCY: VITAFORCE FEROVITE is indicated for the prevention of iron deficiency anaemia in pregnancy.

LACTATION: Folic acid is excreted in breast-milk. The amount of iron and folic acid which is transferred from VITAFORCE FEROVITE to breast-milk has not been determined and it is not known if adverse effects occur in the breastfed infants of mothers who receive VITAFORCE FEROVITE treatment.

DOSAGE AND DIRECTIONS FOR USE

Adults 18 years and older:
Take 1 to 3 tablets daily or as directed by your health care provider.
Tablets to be taken on an empty stomach to enhance iron absorption.

SIDE EFFECTS

Gastrointestinal disorders:
Frequent: faeces discoloured, abdominal bloating, upper abdominal pain, constipation, diarrhoea, nausea.
Skin and subcutaneous tissue disorder:
Less frequent: allergic dermatitis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Signs and symptoms:
Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may occur.
In severe cases after visible transient improvement, relapse may occur after 24-48 hours manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, circulatory failure, convulsions, coma and death.
Chronic overdosage may present as haemosiderosis or haemochromatosis. This is especially likely if anaemia resistant to treatment is erroneously diagnosed as iron deficiency.
Ingestion of a large of overdosage of VITAFORCE FEROVITE requires emergency treatment.
Treatment:
The treatment of mild to moderate poisoning is based on the induction of emesis. It should be borne in mind that perforation may occur in patients, in whom the gastric wall is already damaged. In severe cases of poisoning, particularly if the serum iron concentration exceeds the total iron binding capacity, desferroxamine, an iron-chelating agent, should be administered orally or parenterally as a specific antidote. A solution of 10 g desferroxamine in 50 ml of water should be left in the stomach. Alternatively, a 1 % solution of sodium bicarbonate may be employed, some of which should be left in the stomach. Also give 2 g desferroxamine in 10 ml water for injections by intramuscular injection. Exchange transfusion and surgical treatment must be considered if a potentially lethal dose of VITAFORCE FEROVITE has been ingested and cannot be removed from the gastrointestinal tract with the methods described above. Treatment also includes monitoring of the status of the circulation through standard examination and observation of the other signs, particularly fluid balance and acid-base imbalance. Fluid replacement is essential.

IDENTIFICATION

Light brown speckled round tablet.

PRESENTATION

White plastic container with a white plastic screw cap containing 28, 56, 84, 100, 500 or 1000 tablets.

STORAGE INSTRUCTIONS

Store at or below 25 °C.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Ascendis Supply Chain (Pty) Ltd.
1 Carey Street
Wynberg, Sandton
JOHANNESBURG
2090.
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA

842650/02

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SCHEDULING STATUS: S0

PROPRIETARY NAME (and dosage form):

RESMED FERROUS GLUCONATE SYRUP

COMPOSITION: Each 5 ml contains:

Ferrous Gluconate 350 mg

Preservatives:

Sodium benzoate 0,1% m/v

Methyl hydroxybenzoate 0,2% m/v

Propyl hydroxybenzoate 0,02% m/v

Contains TARTRAZINE

PHARMACOLOGICAL CLASSIFICATION:

A 8.3 Erythropoietics (Haematinics).

PHARMACOLOGICAL ACTION:

Ferrous Gluconate is absorbed from the stomach and small intestine and combines with apoferritin to form ferritin which is stored in the liver, spleen, red bone marrow and intestinal mucosa.

INDICATIONS:

Iron deficiency anaemia.

CONTRA-INDICATIONS:

Ferrous Gluconate should not be given to patients receiving repeated blood transfusions, or in cases of existing haemochromatosis, haemosiderosis or other anaemic conditions, unless accompanied by iron deficiency. It should not be administered concomitantly with parenteral iron.

DOSAGE AND DIRECTIONS FOR USE:

Children under 2 years: 5 - 10 drops

2 to 5 years: 10 - 20 drops

5 to 12 years: 2 - 2,5 ml

Adults & children older than 12 years:

1 - 2 medicine measures

three or four times daily after meals or as directed by the physician.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

The oral administration of iron preparations sometimes produces gastrointestinal irritation, abdominal pain, nausea and vomiting. These irritant adverse effects are usually related to the amount of elemental iron taken rather than the type of preparation. Other gastrointestinal effects may include either diarrhoea or constipation. Adverse effects may be reduced by giving it with or after food rather than on an empty stomach or by beginning therapy with a small dose and increasing gradually. The faeces of patients taking iron salts may be coloured black.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may be fatal, especially in small children. Seek medical attention immediately.

IDENTIFICATION:

A brown liquid.

PRESENTATION:

100 ml amber plastic bottles.

STORAGE INSTRUCTIONS:

Store at or below 25°C. Protect from light. Keep well closed.

KEEP OUT OF REACH OF CHILDREN

REFERENCE NUMBER: H880 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

Resmed Healthcare,

71 Rochdale Road,

Springfield Park, Durban, 4051

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