ALPHA PHARM ALPHA CHELATED IRON

SCHEDULING STATUS
S0

PROPRIETARY NAME (AND DOSAGE FORM)
ALPHA PHARM ALPHA CHELATED IRON, capsules

COMPOSITION

Each capsule contains:		* % NRV (4 years and older)
Iron Chelate 20%	110 mg	
(Supplying elemental Iron)	22 mg	169
Folic acid	400 mcg	100

*NRV (Nutrient Reference Values)

PHARMACOLOGICAL CLASSIFICATION
Complementary Medicine
Category D
Discipline: Health Supplement
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

PHARMACOLOGICAL ACTION AND INDICATIONS
Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative process of living tissues.
Folic acid plays a role in the metabolism of cell division and in the regeneration of blood cells.

CONTRAINDICATIONS
Contraindicated in patients with an allergic hypersensitivity to any of these ingredients.
Not indicated in the treatment of pernicious anaemia. Do not administer concomitantly with parental iron. Should not be given to patients with anaemias not produced by iron deficiency.

WARNINGS AND SPECIAL PRECAUTIONS
This product is not intended to diagnose, treat or cure any ailment. If you are on any chronic medication or diagnosed with a chronic condition contact your healthcare practitioner before taking any supplement. Discontinue use immediately if any adverse reactions occur and contact your healthcare practitioner. Iron and tetracycline absorption is diminished if taken concomitantly. Iron should be administered 3 hours before or 2 hours after the tetracycline. Iron have been reported to decrease the absorption of levodopa, penicillamine, fluoroquinolones, ciprofloxacin and ofloxacin. Iron should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present. Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.
Caution: contains Iron. Overdosage in children is dangerous. Vitamin and mineral supplements should not replace a balanced diet.

INTERACTIONS
Iron and tetracycline absorption is diminished if taken concomitantly. Iron should be administered 3 hours before or 2 hours after the tetracycline. Iron have been reported to decrease the absorption of levodopa, penicillamine, fluoroquinolones, ciprofloxacin and ofloxacin.

PREGNANCY AND LACTATION
Safety in pregnancy and lactation has not been established – do not use.

DOSAGE AND DIRECTIONS FOR USE
Adults: Take 1 capsule a day after a meal.
Do not exceed the recommended daily dosage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
None known at the prescribed daily dosage. Allergic reactions have been reported with vitamin and mineral use and include rash and pruritus. Mild gastro – intestinal distress may be experienced in some people, especially when taken on an empty stomach. May cause mild abdominal discomfort.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Treatment is supportive and symptomatic. Should accidental overdose occur, discontinue use and consult a medical practitioner or seek medical advice.

IDENTIFICATIONS
Maroon capsules

PRESENTATION
30 Capsules in a white container with seal.

STORAGE INSTRUCTIONS
Keep in a dry, cool place below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

MANUFACTURED FOR
Alpha Pharm (Pty) Ltd
Corporate Park 66
Cnr. Von Willich and Lenchen Avenues
Centurion
Tel.: +27 12 643 5840
Manufactured in South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT
December 2018.

CATEGORY D
Discipline: Health Supplement
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ALPHA PHARM ALPHA CHELATED IRON

SKEDULERINGS STATUS
S0

EIENDOMSNAAM EN DOSEERVORM
ALPHA PHARM ALPHA CHELATED IRON, kapsules.

SAMESTELLING

Elke kapsuul bevat:		* % NRV (4 jaar en ouer)
Yster Chelaat 20%	110 mg	
(bevat elementere Yster)	22 mg	169
Foliensuur	400 mcg	100

*NRV (Nutrient Reference Values)

PHARMAKOLOGIESE KLASSIFIKASIE
Komplimentêre Medisyne
Kategorie D
Dissipline: Gesondheids Aanvulling
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

PHARMAKOLOGIESE AKSIE EN INDIKASIE
Yster is 'n noodsaaklike bestanddeel van die liggaam, wat nodig is vir die vorming van hemoglobien en vir die oksidatiewe proses van lewende weefsel.
Foliensuur speel 'n rol in die metabolisme van seldeling en in die herlewing van die bloed selle.

KONTRA-INDIKASIE
Bekende hipersensitiwiteit teenoor enige van die bestandele.
Nie aangedui vir die behandeling van kwaadaardige bloedarmoede nie. Moenie gelyktydig administreer word met parenterale yster nie. Moet nie aan pasiënte gegee word met anemieë wat nie nie deur ystertekort veroorsaak word nie.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS
Hierdie produk is nie bedoel om te diagnoseer, te behandel of enige kwaal te genees nie. As jy op enige chroniese medikasie of gediagnoseer is met 'n chroniese toestand kontak jou dokter voordat enige aanvulling gebruik word. Staak onmiddelik die gebruik indien enige nadelige reaksies plaasvind en kontak jou dokter. Yster en tetrasiklien opname is verminder as gelyktydig geneem word. Yster moet 3 uur voor of 2 ure na die tetrasiklien geneem word. Yster kan die opname van levodopa, penisielamien, fluorokinolones, siprofloksasien en ofloxacin verminder. Yster moet nie gegee word aan pasiënte wat herhaalde bloedoortappings of aan pasiënte met anemieë wat nie deur ystertekort veroorsaak is nie, tensy ystertekort wel ook teenwoordig is. Sorg moet geneem word wanneer aan pasiënte gee met 'n yster-berging of yster-opname siektes, hemoglobinopathieën, of bestaande gastro-intestinale siektes.
Let op: bevat yster. Oordosering in kinders is gevaarlik. Vitamien en mineraal aanvullings moet nie 'n gebalanseerde dieet vervang nie.

INTERAKSIES
Yster en tetrasiklien opname is verminder as gelyktydig geneem word. Yster moet 3 uur voor of 2 ure na die tetrasiklien geneem word. Yster kan die opname van levodopa, penisielamien, fluorokinolone, siprofloksasien en ofloxacin verminder.

SWANGERSKAP EN LAKTASIE
Veiligheid in swangerskap is nie vasgestel nie – moenie gebruik nie.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: Neem kapsule daagliks na 'n maaltyd. Moenie die voorgeskrewe dosis oorskry nie.

NEWE EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Geen bekend as die voorgeskrewe daaglikse dosis gebruik. Allergiese reaksies is aangemeld met vitamien en minerale gebruik en sluit vel uitslag en pruritus in. Ligte gastro - intestinale ongemak kan ervaar word in sommige mense, veral wanneer dit op 'n leë maag gebruik word. Mag matige abdominale ongemak veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Behandeling is ondersteunend en simptomaties. Indien per ongeluk oordoseer, staak die gebruik en raadpleeg 'n geneesheer of kry mediese advies.

IDENTIFIKASIE
Maroon capsules.

AANBIEDING
30 Kapsules in 'n wit houer met seel.

BERGINGSAANWYSINGS
Bewaar op 'n koel, droë plek benede 25 °C.
HOU BUITE BEREIK VAN KINDERS.

VERVAARDIG VIR
Alpha Pharm (Pty) Ltd
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Desember 2018.

KATEGORIE D
Dissipline: Gesondheids Aanvulling
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

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PATIENT INFORMATION LEAFLET

ALPHA PHARM ALPHA CHELATED IRON

SCHEDULING STATUS
S0

PROPRIETARY NAME (AND DOSAGE FORM)
ALPHA PHARM ALPHA CHELATED IRON, capsules.

COMPOSITION

Each capsule contains		* % NRV (4 years and older)
Iron Chelate 20%	110 mg	
(Supplying elemental Iron)	22 mg	169
Folic acid	400 mcg	100

*NRV (Nutrient Reference Values)

GENERAL INFORMATION
If you have any questions about this product, please talk with your doctor, pharmacist, or other health care provider.
It is to be used only by the patient for whom it is prescribed. Do not share it with other people.
If your symptoms do not improve or if they become worse, check with your doctor. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about the product. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this product. This information is not specific medical advice and does not replace information you receive from your health care provider. You must talk with your healthcare provider for complete information about the risks and benefits of using the product.

INDICATION AND USE
Iron is an essential constituent of the body, being necessary for haemoglobin formation and for the oxidative process of living tissues.
Folic acid plays a role in the metabolism of cell division and in the regeneration of blood cells.

INSTRUCTIONS BEFORE TAKING THE MEDICINE
Some medical conditions may interact with the product. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:
- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have liver problems or metabolism problems

CONTRAINDICATIONS
Do not use this product if you are allergic to any of the ingredients
Contact your doctor or health care provider right away if this applies to you.
Not indicated in the treatment of pernicious anaemia. Do not administer concomitantly with parental iron. Should not be given to patients with anaemias not produced by iron deficiency.
WARNINGS AND SPECIAL PRECAUTIONS
This product is not intended to diagnose, treat or cure any ailment. If you are on any chronic medication or diagnosed with a chronic condition contact your healthcare practitioner before taking any supplement. Discontinue use immediately if any adverse reactions occur and contact your healthcare practitioner. Iron and tetracycline absorption is diminished if taken concomitantly. Iron should be administered 3 hours before or 2 hours after the tetracycline. Iron have been reported to decrease the absorption of levodopa, penicillamine, fluoroquinolones, ciprofloxacin and ofloxacin. Iron should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present. Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.
Caution: contains Iron. Overdosage in children is dangerous. Vitamin and mineral supplements should not replace a balanced diet.
INTERACTIONS
This is not a complete list of all interactions that may occur. Ask your health care provider if this product may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine. Iron and tetracycline absorption is diminished if taken concomitantly. Iron should be administered 3 hours before or 2 hours after the tetracycline. Iron have been reported to decrease the absorption of levodopa, penicillamine, fluoroquinolones, ciprofloxacin and ofloxacin.
PREGNANCY AND LACTATION
Safety in pregnancy has not been established – do not take.

INSTRUCTIONS ON HOW TO TAKE THE MEDICINE
Do not share medicines prescribed for you with any other person. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

DOSAGE AND DIRECTIONS FOR USE
Adults: Take 1 capsule a day after a meal.
Do not exceed the recommended daily dosage.
Use as directed by your doctor or pharmacist. Check the label on the medicine for exact dosing instructions.
Take by mouth with food.
If you miss a dose for 1 or more days, there is no cause for concern. If your doctor, pharmacist or healthcare professional recommends that you take it, try to remember your dose every day.
Ask your healthcare provider any questions you may have about how to use the product.

SIDE EFFECTS
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advise.
None known at the prescribed daily dosage. Allergic reactions have been reported with vitamin and mineral use and include rash and pruritus. Mild gastro – intestinal distress may be experienced in some people, especially when taken on an empty stomach. May cause mild abdominal discomfort.
All medicines may cause side effects, but many people have no, or minor, side effects. No COMMON side effects have been reported with this product. Seek medical attention right away if any of these SEVERE side effects occur: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue).
This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Treatment is supportive and symptomatic. Should accidental overdose occurs, discontinue use and consult a medical practitioner or seek medical advice.

STORAGE AND DISPOSAL
Keep in a dry, cool place below 25 °C. ***STORE ALL MEDICINE OUT OF REACH OF CHILDREN.***
Check with your pharmacist about how to dispose safely of unused medicine.

PRESENTATION
30 Capsules in a white container with seal.

IDENTIFICATIONS
Maroon capsules

MANUFACTURED FOR
Alpha Pharm (Pty) Ltd
Corporate Park 66
Cnr. Von Willich and Lenchen Avenues
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Manufactured in South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT
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DISCIPLINE
Category D: Health Supplement
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PASIENT INFORMASIE BROSJURE

ALPHA PHARM ALPHA CHELATED IRON

SKEDULERINGS STATUS
S0.

EIENDOMSNAAM EN DOSEERVORM
ALPHA PHARM ALPHA CHELATED IRON, kapsules.

SAMESTELLING

Elke kapsuul bevat:		* % NRV (4 jaar en ouer)
Yster Chelaat 20%	110 mg	
(bevat elementere Yster)	22 mg	169
Foliensuur	400 mcg	100

*NRV (Nutrient Reference Values)

ALGEMENE INFORMASIE
As u enige vrae oor hierdie produk het, praat met u dokter, apteker of ander gesondheidsorg verskaffer. Dit moet slegs gebruik word deur die pasiënt vir wie dit voorgeskryf is en moenie dit met ander mense deel nie.
As u simptome nie verbeter nie, of as hulle erger raak, gaan praat met u dokter, apteker of ander gesondheidsorg verskaffer. Hierdie inligting onderskryf nie enige medisyne as veilig, doeltreffend of goedgekeur vir enige pasiënt of gesondheid toestand behandeling nie. Dit is net 'n kort opsomming van algemene inligting oor die produk en word nie onderskryf om te diagnoseer, behandel, genees of om enige siekte toestand te verhoed nie. Dit sluit nie al die inligting in, oor die moontlike gebruike, aanwysings, waarskuwings, voorsorgmaatreëls, interaksies, newe-effekte, of risiko's wat van toepassing is op hierdie produk nie. Hierdie inligting is nie spesifieke mediese advies nie, en vervang nie inligting wat u van u dokter, apteker of gesondheidsorg diensverskaffer ontvang nie. Vra u dokter, apteker of gesondheidsorg diensverskaffer vir volledige inligting oor die risiko's en voordele van die gebruik van die produk.

INDIKASIE EN GEBRUIK
Yster is 'n noodsaaklike bestanddeel van die liggaam, wat nodig is vir die vorming van hemoglobien en vir die oksidatiewe proses van lewende weefsel.
Foliensuur speel 'n rol in die metabolisme van seldeling en in die herlewing van die bloed selle.

INSTRUKSIES VOOR DIE MEDISYNE GENEEM MOET WORD
Sommige mediese toestande kan 'n interaksie met hierdie produk he. Raadpleeg jou dokter of apteker indien u enige van die volgende mediese toestande op u van toepassing is:
- As jy swanger is, beplan om swanger te raak, of borsvoed
- Indien u enige voorskrif of nie voorgeskrewe medisyne, kruie of ander annvullings neem.
- As jy allergieë tot medisyne, kos of enige ander stowwe het.
- As jy lewer probleme, of metabolisme probleme het.

KONTRA-INDIKASIE
Bekende hipersensitiwiteit teenoor enige van die bestandele.
Kontak u dokter dadelik as dit op u van toepassing is.
Nie aangedui vir die behandeling van kwaadaardige bloedarmoede nie. Moenie gelyktydig administreer word met parenterale yster nie. Moet nie aan pasiënte gegee word met anemieë wat nie nie deur ystertekort veroorsaak word nie.
WAARSKUWING EN SPESIALE VOORSORGMAATREËLS
Hierdie produk is nie bedoel om te diagnoseer, te behandel of enige kwaal te genees nie. As jy op enige chroniese medikasie of gediagnoseer is met 'n chroniese toestand kontak jou dokter voordat enige aanvulling gebruik word. Staak onmiddelik die gebruik indien enige nadelige reaksies plaasvind en kontak jou dokter. Yster en tetrasiklien opname is verminder as gelyktydig geneem word. Yster moet 3 uur voor of 2 ure na die tetrasiklien geneem word. Yster kan die opname van levodopa, penisielamien, fluorokinolone, siprofloksasien en ofloxacin verminder. Yster moet nie gegee word aan pasiënte wat herhaalde bloedoortappings of aan pasiënte met anemieë wat nie deur ystertekort veroorsaak is nie, tensy ystertekort wel ook teenwoordig is. Sorg moet geneem word wanneer aan pasiënte gee met 'n yster-berging of yster-opname siektes, hemoglobinopathieën, of bestaande gastro-intestinale siektes.
Let op: bevat yster. Oordosering in kinders is gevaarlik. Vitamien en mineraal aanvullings moet nie 'n gebalanseerde dieet vervang nie.
INTERAKSIES
Dit is nie 'n volledige lys van alle interaksies wat mag voorkom nie. Vra jou dokter of hierdie produk met die ander medisyne wat jy neem interaksies kan hê. Gaan praat met jou dokter of gesondheidsorg verskaffer voor jy enige van jou medikasie begin, stop, of die dosis verander. Yster en tetrasiklien opname is verminder as gelyktydig geneem word. Yster moet 3 uur voor of 2 ure na die tetrasiklien geneem word. Yster kan die opname van levodopa, penisielamien, fluorokinolone, siprofloksasien en ofloxacin verminder.
SWANGERSKAP EN LAKTASIE
Veiligheid in swangerskap is nie vasgestel nie – moenie gebruik nie.

INSTRUKSIES OOR HOE OM DIE MEDIKASIE TE GEBRUIK
Moet nooit jou medisyne wat vir jou voorgeskryf is met n ander persoon deel nie.
In die geval van oordosering raadpleeg u dokter of apteker. Indien geen een beskikbaar is nie kontak die naaste hospitaal of gif behandeling sentrum.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: Neem 1 kapsuul daagliks na n maaltyd. Moenie die voorgeskrewe dosis oorskry nie.
Gebruik soos voorgeskryf. Gaan die etiket op die medisyne na vir die presiese dosering instruksies. Neem deur die mond met kos. As jy 'n dosis vir 1 of meer dae mis, is daar geen rede tot kommer nie, maar probeer onthou om jou dosis elke dag te neem soos voorgeskryf. Vra jou dokter, apteker of dokter enige vrae wat jy mag hê oor hoe om die produk te gebruik.

NEWE EFFEKTE
Nie alle newe effekte soos gerapporteer is in die voubiljet ingesluit nie. Indien u algemene gesondheid agteruitgang terwyl u die medikasie neem, raadpleeg asseblief u dokter, apteker of ander mediese gesondheids versorger.
Geen bekend as die voorgeskrewe daaglikse dosis gebruik. Allergiese reaksies is aangemeld met vitamien en minerale gebruik en sluit vel uitslag en pruritus in. Ligte gastro - intestinale ongemak kan ervaar word in sommige mense, veral wanneer dit op 'n leë maag gebruik word. Mag matige abdominale ongemak veroorsaak.
Alle medisyne kan newe-effekte veroorsaak, maar baie mense het geen, of min, newe-effekte. Geen algemene newe-effekte is aangemeld, met gebruik van hierdie produk nie. Kry mediese hulp dadelik as enige van hierdie ernstige newe-effekte voorkom: Erge allergiese reaksies (veluitslag, korwe, jeuk, moeilike asemhaling; benoudheid in die bors; swelsel van die mond, gesig, lippe of tong).
Dit is nie 'n volledige lys van al die newe-effekte wat mag voorkom nie. As jy vrae het oor die newe-effekte, kontak jou dokter, apteker of gesondheidsorg diensverskaffer.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Behandeling is ondersteunend en simptomaties. Indien per ongeluk oordoseer, staak die gebruik en raadpleeg 'n geneesheer of kry mediese advies.

BERGINGSAANWYSINGS EN VERNIETIGING VAN MEDISYNE
Bewaar op 'n koel, droë plek benede 25 °C. ***STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.***
Gaan praat met jou apteker oor hoe om ontslae te raak van ongebruikte medisyne.

AANBIEDING
30 Kapsules in 'n wit plastiek houer met seel.

IDENTIFIKASIE
Maroon capsules.

VERVAARDIG VIR
Alpha Pharm (Pty) Ltd
Corporate Park 66
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
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DISSIPLINE
Kategorie D: Gesondheids Aanvulling
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