PACKAGE LEAFLET: INFORMATION FOR THE USER

SCHEDULING STATUS: [S0]

PROPRIETARY NAME (and dosage form): ALPHA Cardiac Care Capsules 60's

ACTIVE INGREDIENTS: EACH CAPSULE CONTAINS:	**mg PER CAP**	**%NRV***
Crataegus spp (Hawthorn) [Berries], as 100 mg of a 4:1 extract] (DHE)***	400	**
Taurine	150	**
L-Arginine	100	**
Curcuma Longa (Turmeric) Extract [Rhizomes, standardised to 95% Curcuminoids] Providing Curcumin	52.63 50	**
Thiamine HCl (Vitamin B1) Providing Vitamin B1 elemental	11.9 10	833

*NRV (Nutrient Reference Values for persons 4 years and older)

** No NRV established

***DHE =Dried Herb Equivalent

Contains No Sugar, Non-nutritive Sweeteners, colourant or flavourant

Excipients: Magnesium Stearate, Starch

Complementary Medicine, Health Supplement

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.

Keep this leaflet. You may need to read it again.

ALPHA Cardiac Care Capsules is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use ALPHA Cardiac Care Capsules carefully to get the best results from it.

Do not share ALPHA Cardiac Care Capsules with any other person.

Ask your healthcare provider or Pharmacist if you need more information or advice.

What is in this leaflet?

1. What ALPHA Cardiac Care Capsules is, and what it is used for

2. What you need to know before you take ALPHA Cardiac Care Capsules

3. How to take ALPHA Cardiac Care Capsules

4. Possible side effects

5. How to store ALPHA Cardiac Care Capsules

6. Contents of the pack and other information

1. What ALPHA Cardiac Care Capsules is, and what it is used for

The active ingredients of ALPHA Cardiac Care Capsules include Crataegus (Hawthorn) berries which have been known and valued as a cardiac tonic for centuries, as well as the amino acids Taurine and L-Arginine together with Vitamin B1 and Curcumin.

Possible indications for ALPHA Cardiac Care include:

- Support cardiovascular function
- Support normal function of the heart
- Source of amino acids involved in muscle protein synthesis.
- May help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.
- Helps to relieve inflammation (including the heart = myocarditis or pericarditis)
- Effective and low risk phytotherapy for patients with coronary heart disease, atherosclerosis, hypertension or hypercholesterolemia. *Crataegus oxycantha Monograph; Alternative Medicine Review Volume 15 No2.*

2. What you need to know before you take ALPHA Cardiac Care Capsules

Do not take ALPHA Cardiac Care Capsules:

 if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of ALPHA Cardiac Care Capsules (listed in section 6).

 if you are hypersensitive (allergic) to members of the Rose family. (Crataegus)

 if you have been diagnosed with gallstones or a bile duct obstruction (due to the Curcumin content).

 if you are pregnant or breast feeding. (Curcumin)

<u>Warnings and precautions</u>

Keep out of reach of children.

Unless otherwise prescribed, do not exceed the stated daily dose.

Sufficient protein is provided in normal well-balanced daily meals.

If you are using ANY prescribed medication FIRST consult your Doctor or Pharmacist before using ALPHA Cardiac Care Capsules

Consult a relevant health care provider prior to use (due to the Curcumin content) if you:
• are pregnant;
• are taking antiplatelet medication or blood thinners;
• have gallstones or a bile duct obstruction; or
• have stomach ulcers or excess stomach acid.

Consult a relevant health care provider prior to use (due to the Crataegus content) if you:

- are taking blood pressure medication
- are taking cholesterol medication
- are using heart medication (Digitalis or related)

Relief of inflammation:
Consult a relevant health care provider if symptoms persist or worsen.

<u>Other medicines and ALPHA Cardiac Care Capsules</u>

Always tell your healthcare provider if you are taking any other medicine.

Crataegus (Hawthorn) may increase the action of blood pressure medication, cholesterol medication, or heart medication (Digoxin/Digitalis). Consult your health care provider prior to use.

Curcumin may potentially interact with CYP2D6 and CYP3A substrates. Consult your health care provider prior to use.

See Warnings and Precautions

<u>ALPHA Cardiac Care Capsules with food</u>

None known

<u>Pregnancy and breastfeeding</u>

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, **do not use this medicine** as Curcumin may have emmenagogue (increase vomiting) and abortifacient (increase the risk of spontaneous abortion) effects

Safety in pregnancy has not been established.

3. How to take ALPHA Cardiac Care Capsules

Do not share medicines prescribed for you, with any other person.

Take ALPHA Cardiac Care Capsules exactly as described in this leaflet or as prescribed by your Doctor or Pharmacist.

<u>Dosage and Directions for use</u>

Adults: Take 1-2 capsules twice daily or as prescribed by your Doctor or Pharmacist.
Not suitable for use in Children

Do not exceed the stated daily dosage.

<u>If you take more ALPHA Cardiac Care Capsules than you should</u> you may experience dizziness, headache, heart palpitations or gastrointestinal symptoms.

In the event of overdosage, stop using ALPHA Cardiac Care Capsules and consult your Doctor or Pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ALPHA Cardiac Care Capsules, do not take a double dose to make up for forgotten doses.

4. Possible side effects

ALPHA Cardiac Care Capsules can have side effects.

Not all side effects reported for ALPHA Cardiac Care Capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALPHA Cardiac Care Capsules, please consult your healthcare provider for advice.

If any of the following happens, stop taking ALPHA Cardiac Care Capsules and tell your doctor:

 swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

 Rash or itching.

 Diarrhoea, nausea or vomiting

 Dizziness, anxiety, heart palpitations

5. How to store ALPHA Cardiac Care Capsules

Store all medicines out of reach of children.

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

6. Contents of the pack and other information

What ALPHA Cardiac Care Capsules contains

 The active ingredients of ALPHA Cardiac Care are: Crataegus(Hawthorn) extract (100 mg), Taurine (150 mg), L-Arginine (100 mg), Curcumin (50 mg), Vitamin B1 (10 mg)

 Excipients: Magnesium Stearate, Starch

What ALPHA Cardiac Care Capsules looks like and contents of the pack

- white capsules, size 0
- 60 capsules in a silver, PET container with a silver, child resistant lid.

Applicant

Alpha Pharm (Pty) Ltd

Block D Corporate Park 66, Centurion,

Gauteng, ZA

This leaflet was created in

May 2022

PI available from:

Alpha Pharm (Pty) Ltd

www.alphapharmacies.co.za

INLIGTINGSSTUK VIR DIE GEBRUIKER

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (en doseervorm): ALPHA Cardiac Care Capsules 60's

AKTIEWE BESTANDDELE:

ELKE KAPSULE BEVAT:	PER KAPSULE	%NRV*
Crataegus spp (Hawthorn) [Bessies], as 100 mg van 'n 4:1 uittreksel] (DHE)***	400	**
Taurine	150	**
L-Arginien	100	**
Curcuma Longa (Borrie) uittreksel [Risome, gestandardiseer tot 95% Curcuminoiëde] Verskaf Curcuma	52.63 50	** **
Tiamien HCl (Vitamien B1) Verskaf Vitamien B1 elemental	11.9 10	** 833

*NRV (Nutrient Reference Values vir persone 4 jaar en ouer)

** Geen NRV vasgestel nie

*** DHE =Dried Herb Equivalent

Bevat GEEN Suiker, Versoeters, kleursel of geursel nie.

Onaktiewe Bestanddele: Magnesiumstearaat, Stysel

Komplementêre Medisyne, Gesondheids Aanvulling

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

Lees die hele voubiljet aandagtig deur aangesien dit belangrike inligting vir u bevat.

Hou hierdie voubiljet. U mag dit dalk later weer benodig.

ALPHA Cardiac Care Capsules is beskikbaar sonder 'n voorskrif om vir u in staat te stel om u gesondheid te onderhou. Nietemin moet u steeds ALPHA Cardiac Care Capsules sorgvuldig aanwend om die beste resultate daaruit te verkry.

Moet nie ALPHA Cardiac Care Capsules met enige ander persoon deel nie.

Vra u Gesondheidspraktisyn of Apteker indien u verdere inligting of advies benodig.

Wat is in hierdie inligtingsstuk?

1. Wat is ALPHA Cardiac Care Capsules en waarvoor word dit gebruik?

2. Wat u moet weet alvorens u ALPHA Cardiac Care Capsules gebruik

3. Hoe om ALPHA Cardiac Care Capsules in te neem

4. Moontlike newe-effekte

5. Hoe om ALPHA Cardiac Care Capsules te stoor

6. Inhoud van die houer en verdere inligting

1. Wat is ALPHA Cardiac Care Capsules en waarvoor word dit gebruik?

Die aktiewe bestanddele van ALPHA Cardiac Care Capsules sluit in Crataegus (Meidoorn) bessies wat al eeue lank as 'n baie effektiewe harttonikum bekend staan en aangewend word, asook die aminosure Taurine en L-arginien tesame met Vitamien B1 en Curcuma.

Moontlike aanwendings vir ALPHA Cardiac Care sluit in:

- Ondersteun kardiovaskulêre funksie
- Ondersteun normale funksionering van die hart
- Bron van aminosure wat benodig word vir die sintese van spierproteïne.
- Mag help om 'n verbetering in die kapasiteit vir oefening te bewerkstellig in mense met stabiele kardiovaskulêre kondisies.
- Help om inflammasie te verlig (insluitend die hart = miokarditis of perikarditis)
- Effektiewe en lae risiko fitoterapie vir pasiënte met koronêre hartsiekte, aterosklerose, hipertensie of hipercholesterolemie *Crataegus oxycantha Monograph; Alternative Medicine Review Volume 15 No2.*

2. Wat u moet weet alvorens u ALPHA Cardiac Care Capsules gebruik

Moet nie ALPHA Cardiac Care Capsules gebruik nie indien:

 u hipersensitief (allergies) is vir enige van die aktiewe of ander bestanddele van ALPHA Cardiac Care Capsules (gelys onder afdeling 6).

 u hipersensitief (allergies) is vir enige van die lede van die Roos-familie (Crataegus)

 u gediagnoseer is met galstene of 'n obstruksie van die galbuis (as gevolg van die Curcuma inhoud).

 u swanger is of borsvoed (Curcuma)

<u>Waarskuwings en Spesiale Voorsorgmaatreëls</u>

Hou buite bereik van kinders.

Tensy anders voorgeskryf, moenie die aanbevole dosis oorskry nie.

Voldoende proteine word verskaf deur gewone, gebalanseerde maaltye.

Indien u ENIGE voorgeskrewe medisyne gebruik raadpleeg u Geneesheer of Apteker ALVORENS u ALPHA Cardiac Care Capsules gebruik

Raadpleeg 'n gesondheidspraktisyn alvorens u ALPHA Cardiac Care gebruik (as gevolg van Curcuma inhoud) indien u:

- Swanger is
- Anti-plaatjie middels of bloeverdunners gebruik
- Gediagnoseer is met galstene of 'n galbuisobstruksie
- Aan maagswere of te veel maagsuur ly.

Raadpleeg 'n gesondheidspraktisyn alvorens u ALPHA Cardiac Care gebruik (as gevolg van Crataegus inhoud) indien u:

- Bloeddrukmedikasie gebruik
- Cholesterolmedikasie gebruik
- Hartmedikasie gebruik(Digitalis of verwant)

Verligting van Inflammasie:
Raadpleeg 'n gesondheidspraktisyn indien simptome aanhou of vererger .

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<u>Ander medisynes en ALPHA Cardiac Care Capsules</u>

Noem dit altyd vir u gesondheidspraktisyn indien u enige ander medikasie gebruik.

 Crataegus (Meidoorn) mag die werking van bloeddruk medikasie, cholesterol medikasie of hart medikasie (Digoxin/Digitalis) verhoog. Raadpleeg u gesondheidpraktisyn alvorens u ALPHA Cardiac Care Capsules gebruik.

 Curcuma mag moontlik die werking van CYP2D6 en CYP3A substrate verander. Raadpleeg u gesondheidpraktisyn alvorens u ALPHA Cardiac Care Capsules gebruik.

Sien Waarskuwings en Spesiale Voorsorgmaatreëls.

<u>ALPHA Cardiac Care Capsules en voedsel</u>

Geen bekend

<u>Swangerskap en Laktasie</u>

Indien u swanger is of borsvoed, dink dat u dalk swanger mag wees of beplan om swanger te raak, moet **u nie hierdie medisyne gebruik nie** aangesien Curcuma tot verhoogde vomering of 'n verhoogde moontlikheid van spontane aborsie mag aanleiding gee.

Veiligheid in swangerskap is nie vasgestel nie.

3. Hoe om ALPHA Cardiac Care Capsules in te neem

Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Neem ALPHA Cardiac Care Capsules presies soos in hierdie inligtingsstuk beskryf, of soos deur u Geneesheer of Apteker voorgeskryf.

<u>Dosis en Gebruiksaanwysings</u>

Volwassenes: Neem 1-2 kapsules twee keer daagliks of soos voorgeskryf deur jou Dokter of Apteker.
Nie geskik vir gebruik deur kinders nie.

Moenie die aanbevole dosis oorskry nie.

Indien u meer ALPHA Cardiac Care Capsules inneem as u moes, mag u dalk duiseligheid, kopseer, hartkloppings of dermprobleme ondervind.

In die geval van oordosering, staak die gebruik van ALPHA Cardiac Care Capsules en raadpleeg u Geneesheer of Apteker. Indien geen een beskikbaar is nie, kontak u naaste hospitaal of gifbehandelingssentrum.

Indien u vergeet om ALPHA Cardiac Care Capsules in te neem, moenie 'n dubbele dosis inneem om te vergoed vir die vergete dosis nie.

4. Moontlike newe-effekte

ALPHA Cardiac Care Capsules mag newe-effekte hê.

Nie alle newe-effekte van ALPHA Cardiac Care Capsules soos gerapporteer, is in die inligtingsstuk ingesluit nie. Indien u algemene gesondheid agteruit gaan of u enige onverwagte effekte ondervind terwyl u ALPHA Cardiac Care Capsules neem, raadpleeg asseblief u Gesondheidspraktisyn.

Indien enige van die volgende voorkom, staak die inname van ALPHA Cardiac Care Capsules en raadpleeg u Geneesheer:

- opswel van hande, voete, enkels, gesig, lippe en mond of keel wat asemhaling of sluk mag belemmer .
- uitslag of jeuk.
- Diarree, naarheid of braking
- Duiseligheid, angstigheid, hartkloppings

5. Hoe om ALPHA Cardiac Care Capsules te stoor

Hou alle medisyne buite bereik van kinders.

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

6. Inhoud van die houer en ander inligting

Wat ALPHA Cardiac Care Capsules bevat

- Die aktiewe bestanddele van ALPHA Cardiac Care is: Crataegus(Meidoorn) uittreksel (100 mg), Taurine (150 mg), L-Arginien (100 mg), Curcuma (50 mg), Vitamien B1 (10 mg)
- Onaktiewe bestanddele: Magnesiumstearaat, Stysel

Hoe ALPHA Cardiac Care Capsules lyk en inhoud van die houer:

- Wit kapsules, grootte 0
- 60 kapsules in 'n silwer PET-plastiekhouer met 'n silwer kinderbestande deksel.

<u>Aansoeker</u>

Alpha Pharm (Pty) Ltd

Block D Corporate Park 66, Centurion,

Gauteng, ZA

<u>Hierdie Inligtingsstuk is opgestel in:</u>

Mei 2022

<u>PI beskikbaar by:</u>

Alpha Pharm Pty Ltd

www.alphapharmacies.co.za