

PROFESSIONAL INFORMATION**Complementary Medicine: Health Supplement**

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

SCHEDULING STATUS: S0**1. NAME OF THE MEDICINE**

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C vegetable capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

	720 mg
[providing 500 mg ascorbic acid (vitamin C)]	

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

White vegetable capsule containing a white/off-white to light pink powder.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

Vitamin C is an essential vitamin for the maintenance of good health. It is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

4.2 Posology and method of administration**Adults and children 6 years and older:**

Take one vegecapsule daily.

4.3 Contraindications

- Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Caution should be advised in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, kidney disease, or a history of oxalate kidney stone formation.

4.5 Interaction with other medicines and other forms of interaction

- Vitamin C may reduce the activity of warfarin.
- Iron excretion induced by desferrioxamine is enhanced by the administration of vitamin C.
- Vitamin C may increase plasma estrogen levels of estrogen-containing oral contraceptives.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C does not adversely affect their performance.

4.8 Undesirable effects**Gastrointestinal disorders**

Frequent: abdominal cramps, esophagitis, heartburn, headache, diarrhoea, nausea, vomiting.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.11 Vitamins.

5.1 Pharmacodynamic properties

Vitamin C is an essential vitamin for the maintenance of good health. It is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Amber glass bottle with a gold-coloured, child-resistant screw cap lid, packed into an outer carton.

Pack size: 30 vegetable capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for the Dis-Chem Group
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@dischem.co.za
0860 347 243
www.dischem.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

SO

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C (vegetable capsules)

Complementary Medicine: Vitamins (Health Supplement)

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

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

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C carefully to get the best results from it.

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

- Do not share DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C with any other person.

- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is and what it is used for.
2. What you need to know before you use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.
3. How to use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.
4. Possible side effects.
5. How to store DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.
6. Contents of the pack and other information.

1. What DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is and what it is used for

Vitamin C is an essential vitamin for the maintenance of good health. It is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

2. What you need to know before you use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- If you have a kidney disease, or have a history of oxalate kidney stone formation.

Children and adolescents

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is not recommended for individuals below the age of 6 years.

Other medicines and DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use if you are taking any other medication, as DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C may alter their effectiveness.

Consult a healthcare practitioner prior to use if you are taking any of the following medications: warfarin, desferrioxamine, oral contraceptives.

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 practitioner for advice before using DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C does not adversely affect their performance.

3. How to use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 6 years and older

Take one vegecapsule daily, or as recommended by your healthcare practitioner.

4. Possible side effects

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C can have side effects. Not all side effects reported for DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital:

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

These are very serious side effects. If you have them, you may have had a serious reaction to DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following: abdominal cramps, esophagitis, heartburn, headache, diarrhoea, nausea, vomiting.

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

Reporting of side effects

If you experience side effects, inform 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 DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.

5. How to store DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C to your pharmacist.
- Do not dispose of unused DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C contains

Each vegetable capsule contains:

Liposomal Vitamin C (CELLg8® C)

[providing 500 mg ascorbic acid (vitamin C)]

720 mg

Other ingredients: magnesium stearate.

Sugar free

Presentation and identification of DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

White vegetable capsules containing a white/off-white to light pink powder, in an amber glass bottle with a gold-coloured, child-resistant screw cap lid, packed into an outer carton.

Pack size: 30 vegetable capsules.

Holder of Certificate of Registration

Manufactured for: The Dis-Chem Group, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685 Careline: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

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PATIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

SO

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C (groentekapsules)

Komplementêre Medisyne: Vitamiene (Gesondheidsaanvulling)

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

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

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyen van apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C gebruik.
3. Hoe om DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C te gebruik.
4. Moontlike newe-effekte.
5. Hoe om DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is en waarvoor dit gebruik word

Vitamiene is 'n noodsaaklike vitamien vir die handhawing van goeie gesondheid. Dit is 'n antioksident wat bydra tot die beskerming van selle teen vrye radikale skade. Dit dra by tot die normale funksie van die immuunsysteem en die senuweestelsel. Dit help met normale kollageenvorming en die vermindering van tamheid en moegheid.

2. Wat u moet weet voordat u DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C gebruik

'n Gevarieerde diete is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal.

Moenie DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C neem nie:

- Indien u hypersensitief (allergie) is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwing en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyen voordat u DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyen voor gebruik:

- Indien u glukose-6-fosfaat dehidrogenase (G6PD) tekort het.
- Indien u 'n niersiekte het, of indien u 'n geskiedenis van oksalaat nierstene het.

Kinders en adolescentes

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C word nie aanbeveel vir individue onder die ouderdom van 6 jaar nie.

Die neem van DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C en ander medisyne

Lig altyd 'n gesondheidsorgpraktisyen in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamphlet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyen voor gebruik indien u enige ander medisyne neem, aangesien DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C hul doeltreffendheid kan verander.

Raadpleeg 'n gesondheidsorgpraktisyen voor gebruik indien u enige van die volgende medisyne neem: warfarin, desferrioxamine, orale voorbehoedmiddels.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyen vir advies voordat u DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur van masjinerie gebruik, totdat hulle redelik seker is dat DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daagliks dosis oorskry nie. Gebruik DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyen. Raadpleeg u gesondheidsorgpraktisyen indien u nie seker is nie.

Volwassenes en kinders 6 jaar en ouer

Neem een vegekapsule daagliks, of soos aanbeveel deur u gesondheidsorgpraktisyen.

4. Moontlike newe-effekte

DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C kan newe-effekte hê. Nie alle newe-effekte vir DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksieserva tydens die gebruik van DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyen vir advies. As een van die volgende gebeur, hou op met die gebruik van DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal:

- swelling van u hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal;
- veluitslag of gejeuk;
- floutes.

Hierdie is baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie teen DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Sê vir u dokter indien u enige van die volgende opmerk: abdominale krampe, esofagitis, sooibrand, hoofpyn, diarrée, naarheid, braking.

Lig asseblief u dokter of apteker in indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuks genoem word nie.

Rapportering van newe-effekte

Praat met u dokter of apteker as u newe-effekteerva. U kan ook newe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C.

5. Hoe om DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BIJTE BEREIK VAN KINDERS.

• Moenie gebruik na die vervalddatum op die etiket nie.

• Neem alle ongebruikte DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C na u apteker terug.

• Moenie ongebruikte DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C in afvoerpipe of riuolsisteme (bv. toilette) weggoei nie.

6. Inhoud van die verpakking en ander inligting

Wat DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C bevat

Elke groentekapsule bevat:

Liposomale Vitamien C (CELLg8® C)

[verskaf 500 mg askorbiensuur (vitamien C)]

720 mg

Ander bestanddele: magnesiumstearaat.

Suiker

Aanbieding en identifikasie van DIS-CHEM GOLD+ LIPOSOMAL VITAMIN C

Wit groentekapsules wat 'n wit/af-wit tot ligpienk poeier bevat, in 'n bruin glasbottel met 'n goudkleurige, kinderbestande skroefdop, verpak in 'n buitenste kartonhouer. Verpakkingsgrootte: 30 groentekapsules.

Houer van Registrasiesertifikaat

Vervaardig vir: The Dis-Chem Group, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685 Sorglyn: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

Hierdie pamphlet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.