

PROFESSIONAL INFORMATION

Complementary Medicine: Combination Product

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+ BERBERINE & GREEN TEA vegetable capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Berberine Hydrochloride [from <i>Berberis aristata</i>]	500 mg
Greenselect™ Phytosome® Technology [<i>Camellia sinensis</i> (Green Tea) decaffeinated leaf, 6 - 15:1 extract providing 9,5 mg - 12,5 mg catechins]	50 mg
Chromium (as Chromium Polynicotinate)	50 µg

Greenselect™ and Phytosome® are trademarks of Indena S.p.A., Italy.

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

White vegetable capsule containing a brownish yellow powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD+ BERBERINE & GREEN TEA supports normal blood glucose levels and healthy glucose metabolism.

4.2 Posology and method of administration

Adults 18 years and older:

Take one vegecapsule two to three times daily with food.

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 a liver disorder or disease, iron deficiency, behavioral or psychiatric disorders, or kidney disease.

4.5 Interaction with other medicines and other forms of interaction

- Berberine and chromium may have additive effects when used concomitantly with diabetes medication and/or insulin, thereby increasing the risk of hypoglycaemia. Dose adjustments may be required.
- Berberine, green tea and chromium may increase the risk of bleeding when used concomitantly with other anticoagulant medications.
- Berberine, green tea and chromium may increase the risk of bleeding when used concomitantly with warfarin.
- Berberine may have additive effects when used concomitantly with other antihypertensive medications.
- Berberine may increase the sedative effects of CNS depressants.
- Berberine can increase serum levels of cyclosporine and should not be used concomitantly.
- Berberine may reduce the therapeutic effects of losartan by decreasing its conversion to its active form.
- Berberine can reduce metabolism of midazolam, which may increase the risk of severe adverse effects.
- Berberine may increase the sedative effect of pentobarbital.
- Berberine has been associated with increased blood levels of tacrolimus when taken concomitantly.
- Green tea extract can reduce the levels and clinical effects of atorvastatin.
- Green tea can reduce the levels and clinical effects of nadolol.

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+ BERBERINE & GREEN TEA does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequency unknown: diarrhoea, constipation, flatulence, nausea, vomiting, abdominal pain, abdominal distention, bitter taste, dyspepsia, reflux, morning anorexia, increased thirst, decreased appetite.

Skin disorders

Frequency unknown: rash, skin irritation.

Neurological disorders

Frequency unknown: headache, dizziness, paresthesia, insomnia, vertigo.

Psychiatric disorders

Frequency unknown: irritability, mood changes.

Hepatic disorders

Frequency unknown: hepatotoxicity, elevated liver enzymes.

Musculoskeletal disorders

Frequency unknown: muscle pain.

Endocrine disorders

Frequency unknown: hypoglycaemia.

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 33.7 Combination Product

5.1 Pharmacodynamic properties

DIS-CHEM GOLD+ BERBERINE & GREEN TEA supports normal blood glucose levels and healthy glucose metabolism.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD+ BERBERINE & GREEN TEA.

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: 60 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



DIS-CHEM GOLD+ BERBERINE & GREEN TEA (vegetable capsules)

Complementary Medicine: Combination Product

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

- Keep this leaflet. You may need to read it again.
- Do not share DIS-CHEM GOLD+ BERBERINE & GREEN TEA 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+ BERBERINE & GREEN TEA is and what it is used for.
2. What you need to know before you use DIS-CHEM GOLD+ BERBERINE & GREEN TEA.
3. How to use DIS-CHEM GOLD+ BERBERINE & GREEN TEA.
4. Possible side effects.
5. How to store DIS-CHEM GOLD+ BERBERINE & GREEN TEA.
6. Contents of the pack and other information.

1. What DIS-CHEM GOLD+ BERBERINE & GREEN TEA is and what it is used for

DIS-CHEM GOLD+ BERBERINE & GREEN TEA supports normal blood glucose levels and healthy glucose metabolism.

2. What you need to know before you use DIS-CHEM GOLD+ BERBERINE & GREEN TEA

Do not use DIS-CHEM GOLD+ BERBERINE & GREEN TEA:

- 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+ BERBERINE & GREEN TEA, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have a liver disorder or disease, iron deficiency, a behavioural or psychiatric disorder, or a kidney disease.

Children and adolescents

DIS-CHEM GOLD+ BERBERINE & GREEN TEA is not recommended for individuals below the age of 18 years.

Other medicines and DIS-CHEM GOLD+ BERBERINE & GREEN TEA

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+ BERBERINE & GREEN TEA may alter their effectiveness.

Consult a healthcare practitioner prior to use if you are taking any of the following medications: diabetes medication, insulin, anticoagulants, warfarin, antihypertensive medication, CNS depressants, cyclosporine, losartan, midazolam, pentobarbital, tacrolimus, atorvastatin, nadolol.

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+ BERBERINE & GREEN TEA.

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+ BERBERINE & GREEN TEA does not adversely affect their performance.

3. How to use DIS-CHEM GOLD+ BERBERINE & GREEN TEA

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

Adults 18 years and older

Take one vegetable capsule two to three times daily with food, or as recommended by your healthcare practitioner.

4. Possible side effects

DIS-CHEM GOLD+ BERBERINE & GREEN TEA can have side effects. Not all side effects reported for DIS-CHEM GOLD+ BERBERINE & GREEN TEA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM GOLD+ BERBERINE & GREEN TEA, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using DIS-CHEM GOLD+ BERBERINE & GREEN TEA 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+ BERBERINE & GREEN TEA. You may need urgent medical attention or hospitalisation. Tell your doctor as soon as possible if you notice any of the following: diarrhoea, constipation, flatulence, nausea, vomiting, abdominal pain, abdominal distention, bitter taste, dyspepsia, reflux, morning anorexia, increased thirst, decreased appetite, rash, skin irritation, headache, dizziness, paresthesia, insomnia, vertigo, irritability, mood changes, muscle pain, hypoglycemia.

Discontinue use and tell your doctor immediately if you develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.

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+ BERBERINE & GREEN TEA.

5. How to store DIS-CHEM GOLD+ BERBERINE & GREEN TEA

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

6. Contents of the pack and other information

What DIS-CHEM GOLD+ BERBERINE & GREEN TEA contains

Each vegetable capsule contains:

Berberine Hydrochloride 500 mg

[from *Berberis aristata*]

Greenselect™ Phytosome® Technology 50 mg

[*Camellia sinensis* (Green Tea) decaffeinated leaf,

6 - 15:1 extract providing 9,5 mg - 12,5 mg catechins]

Chromium (as Chromium Polynicotinate) 50 µg

Other ingredients: magnesium stearate.

Greenselect™ and Phytosome® are trademarks of Indena S.p.A., Italy.

Sugar free

Presentation and identification of DIS-CHEM GOLD+ BERBERINE & GREEN TEA

White vegetable capsules containing a brownish yellow powder, in an amber glass bottle with a gold-coloured, child-resistant screw cap lid, packed into an outer carton.

Pack size: 60 vegetable capsules.

Holder of Certificate of Registration

Manufactured for: The Dis-Chem Group, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Caroline: 0860 347 243; caroline@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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PASIÉNTINLIGTINGSBLAD SKEDULERINGSSTATUS



DIS-CHEM GOLD+ BERBERINE & GREEN TEA (groentekapsules)

Komplementêre Medisyne: Kombinasieprodukt

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+ BERBERINE & GREEN TEA is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet DIS-CHEM GOLD+ BERBERINE & GREEN TEA 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+ BERBERINE & GREEN TEA met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat DIS-CHEM GOLD+ BERBERINE & GREEN TEA is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u DIS-CHEM GOLD+ BERBERINE & GREEN TEA gebruik.
3. Hoe om DIS-CHEM GOLD+ BERBERINE & GREEN TEA te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om DIS-CHEM GOLD+ BERBERINE & GREEN TEA te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat DIS-CHEM GOLD+ BERBERINE & GREEN TEA is en waarvoor dit gebruik word

DIS-CHEM GOLD+ BERBERINE & GREEN TEA ondersteun normale bloedglukosevlakke en gesonde glukosemetabolisme.

2. Wat u moet weet voordat u DIS-CHEM GOLD+ BERBERINE & GREEN TEA gebruik

Moet nie DIS-CHEM GOLD+ BERBERINE & GREEN TEA neem nie:

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

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u DIS-CHEM GOLD+ BERBERINE & GREEN TEA gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u lewerverstoring of -siekte, ystertekort, 'n gedrags- of psigiatriese verstoring, of 'n niersiekte het.

Kinders en adolessente

DIS-CHEM GOLD+ BERBERINE & GREEN TEA word nie aanbeveel vir individue onder die ouderdom van 18 jaar nie.

Die neem van DIS-CHEM GOLD+ BERBERINE & GREEN TEA en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige ander medisyne neem, aangesien DIS-CHEM GOLD+ BERBERINE & GREEN TEA hul doeltreffendheid kan verander.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige van die volgende medisyne neem: diabetesmedikasie, insulien, antikoagulante, warfarin, antihypertensiewe medikasie, SSS-depressante, siklosporien, losartan, midazolam, pentobarbital, takrolimus, atorvastatin, nadolol.

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 gesondheidsorgpraktisyn vir advies voordat u DIS-CHEM GOLD+ BERBERINE & GREEN TEA 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 of masjinerie gebruik, totdat hulle redelik seker is dat DIS-CHEM GOLD+ BERBERINE & GREEN TEA nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om DIS-CHEM GOLD+ BERBERINE & GREEN TEA te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik DIS-CHEM GOLD+ BERBERINE & GREEN TEA presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes 18 jaar en ouer

Neem een vegekapsule twee tot drie keer daaglik saam met kos, of soos aanbeveel deur u gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

DIS-CHEM GOLD+ BERBERINE & GREEN TEA kan nuwe-effekte hê. Nie alle nuwe-effekte vir DIS-CHEM GOLD+ BERBERINE & GREEN TEA is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van DIS-CHEM GOLD+ BERBERINE & GREEN TEA, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van DIS-CHEM GOLD+ BERBERINE & GREEN TEA 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 nuwe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie op DIS-CHEM GOLD+ BERBERINE & GREEN TEA gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Sê vir u dokter so gou as moontlik indien u enige van die volgende opmerk: diarree, hardlywigheid, winderigheid, naarheid, braking, abdominale pyn, abdominale distensie, bitter smaak, dispepsie, reflux, oggendanoreksie, verhoogde dors, verminderde eetlus, veluitslag, velirritasie, hoofpyn, duiseligheid, parestasie, slapelootheid, vertigo, prikkelbaarheid, gemoedsveranderinge, spierpyn, hipoglukemie.

Staak gebruik en sê vir u dokter dadelik indien u simptome van lewerprobleme ontwikkel soos vergeling van die vel/oë (geelsug), maagpyn, donker urine, sweet, naarheid, ongewone moegheid en/of verlies van eetlus.

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

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van DIS-CHEM GOLD+ BERBERINE & GREEN TEA.

5. Hoe om DIS-CHEM GOLD+ BERBERINE & GREEN TEA te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Stoor in die oorspronklike verpakking en hou die houer dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte DIS-CHEM GOLD+ BERBERINE & GREEN TEA na u apteker terug.
- Moenie ongebruikte DIS-CHEM GOLD+ BERBERINE & GREEN TEA in afvoertyppe of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat DIS-CHEM GOLD+ BERBERINE & GREEN TEA bevat

Elke groentekapsule bevat:

Berberien Hydrochloried 500 mg

[van *Berberis aristata*]

Greenselect™ Phytosome® Technology 50 mg

[*Camellia sinensis* (Groentee) kafeienvrye blaar,

6 - 15:1 ekstrak wat 9,5 mg - 12,5 mg catechins verskaf]

Chroom (as Chroompolinikotinaat) 50 µg

Ander bestanddele: magnesiumstearaat.

Greenselect™ en Phytosome® is handelsmerke van Indena S.p.A., Italië.

Suikervry

Aanbieding en identifikasie van DIS-CHEM GOLD+ BERBERINE & GREEN TEA

Wit groentekapsules wat 'n bruinerige-geel poeier bevat, in 'n bruin glasbottel met 'n goudkleurige, kinderbestande skroefop, verpak in 'n buitenste kartonhouer.

Verpakkingsgrootte: 60 groentekapsules.

Houer van Registrasiesertifikaat

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

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.