

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 vegetable capsule 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.

