

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 ACTIVATED CHARCOAL vegetable capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

| | |
|--------------------|--------|
| Activated Charcoal | 160 mg |
|--------------------|--------|

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 0, clear vegetable capsules containing a grey powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD ACTIVATED CHARCOAL supports the digestive function.

4.2 Posology and method of administration

Adults 18 years and older:

Take one to two vegcapsules up to three times daily, after meals.

Do not exceed the recommended dosage.

Consult a healthcare practitioner prior to use for individuals under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to activated charcoal or to any of the excipients listed in section 6.1.
- Do not use DIS-CHEM GOLD ACTIVATED CHARCOAL if you have intestinal obstruction.

4.4 Special warnings and precautions for use

- Patients who have decreases peristalsis should use activated charcoal with caution and under supervision of a healthcare practitioner.

4.5 Interaction with other medicines and other forms of interaction

Activated charcoal reduces the systemic exposure to many medications, including those that undergo enterohepatic recirculation, regardless of the route of administration, and co-administration should be avoided.

- **Alcohol:** the binding action of activated charcoal may be reduced by alcohol by lowering alcohol's absorptive capacity.
- **Ipecac:** syrup of ipecac is absorbed and inactivated by activated charcoal.
- **Oral contraceptives:** activated charcoal may reduce the clinical effects of oral contraceptives.

4.6 Fertility, pregnancy and lactation

Safety in fertility, 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 ACTIVATED CHARCOAL does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: constipation, black stools, abdominal pain, bloating, flatulence.

Frequency unknown: gastrointestinal obstruction.

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. Health care 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 34.13 Other.

5.1 Pharmacodynamic properties

Activated charcoal supports the digestive function. Activated has been shown to absorb gases, suggesting that it might have a role in reducing flatulence after gas-producing meals.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD ACTIVATED CHARCOAL.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Maize starch
Magnesium stearate

Vegetable capsule shell:

Hypromellose

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C and protect from sunlight and moisture.

6.5 Nature and contents of container

Glass amber bottle with a gold child-resistant screw cap.
Pack size: 60 and 120 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, South Africa

0860 347 243

careline@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.